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14. ABSTRACT Most of the proposed studies have cleared local and HSRRB approvals and are in various stages of implementation at participating sites. Those that have yet to be approved are through the planning phase. For completed studies, results have been analyzed and manuscripts are being prepared for submission to academic conferences and peer reviewed journals. The JVN application has been integrated to include both eye care and diabetes care in readiness for integration into AHLTA. Technologically, we have incorporated a new digital video camera for the eye care component of the JVN program; this is currently undergoing clinical validation for diagnostic accuracy for diabetic retinopathy assessment. CDMF development for new modules is being accomplished and we have expanded the patient portal to encompass many more home monitoring devices. CDMF development has also addressed the results of the completed Human Factors Study (Usability Lab).					
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INTRODUCTION

The major goals of this continuing project are the establishment of a telemedicine system for comprehensive diabetes management and the assessment of diabetic retinopathy that a) provides increased access for diabetic patients to appropriate care, b) centralizes the patients in the care process, c) empowers the patient to better manage their disease, d) can be performed in a cost effective manner, and e) maintains the high standard of care required for the appropriate management of diabetic patients.

The aim of this continuation will be to perform the appropriate clinical validation, cost efficiency, and risk benefit studies associated with the use of the recently developed Comprehensive Diabetes Management Program (CDMP) and the Joslin Vision Network (JVN) Eye Health Care Program that is now a module of the CDMP. This proposal will also have a secondary focus of continuing the ongoing research associated with the development of new modules for the CDMP, and the development and validation of computer algorithms designed to automate detection of retinal lesions developed during the course of retinopathy development.

The need for diabetes disease management is driven by the knowledge that diabetes is not currently curable; but it is treatable and its complications are preventable through optimal care- and self-management. However, the traditional physician-centered, episodic, acute-care model is not designed to optimize care-and self-management, especially with large numbers of diabetic patients (2,200 new cases diagnosed every day in the US). To do requires that the health care delivery system be re-engineered. Such re-engineering is a reality with the use of the CDMP developed under this collaborative effort.

BODY

Summarized below is the originally proposed Statement of Work (SOW) for reference:

1. Prospective multi center cost efficiency study performed using the JVN Telehealth Eye Care module
2. Prospective multi-center risk benefit study using the JVN Telehealth Eye Care module
3. JVN Telehealth CDMP program usability and impact on clinical workflow study
4. Prospective multi-center clinical outcomes efficacy and cost efficiency study using the JVN Telehealth Comprehensive Diabetes Management Program
5. Clinical validation of the Behavior Assessment Tool (BAT) developed for the JVN Telehealth CDMP application
6. Development and validation of Learning Level Assessment and Readiness to Learn tools for the JVN Telehealth CDMP application
7. Deployment of JVN Telehealth CDMP application in Tripler Army Medical Center and Honolulu VA in Hawaii
8. Deployment of JVN Telehealth CDMP application in VA VISN 1 network
9. Deployment of JVN Telehealth CDMP application into the Department of Defense TRICARE Online computer system
10. Establish a centralized JVN Telehealth clinical coordination center to facilitate the proposed multicenter clinical trials
11. Clinical validation of the JVN Eye Care computer algorithm for automation of detection of retinal lesions
12. Clinical validation study for the JVN developed retinal imaging device
13. Automation of the retinal image taking process using the JVN developed retinal imaging device
14. Migration of JVN Eye Care module to Microsoft .Net operating platform
15. Development of additional modules for the JVN Telehealth CDMP application to include an outcomes and reporting module, an education scheduling and tracking tool, a knowledge assessment tool, a nutrition module, a patient portal module, integration of wireless home monitoring devices, and a primary care practitioner module

The proposed prospective studies noted above are summarized below at a program level and further progress summaries are presented that are specific to each participating site. Additional progress on other efforts are also presented in each site section summary. The participating sites are Joslin Diabetes Center, Department of Defense at Walter Reed Army Medical Center, VA at VAMC Jamaica Plain campus in Boston, and the participants through University of Hawaii.

Summary Status Report for Research Projects Supported by the DoD Collaborative (SOW # 1 to #5)

The DoD collaborative has 9 research projects planned, to take place at 4 sites. These each entail testing some aspect of the Comprehensive Diabetes Management Program, namely the Joslin Vision Network (JVN), the Behavioral Assessment Tool (BAT), and the digital photography component of the nutrition module. In

addition, we are working with the American Institutes for Research (AIR) to complete a human factors study of the CDMP; there was a research component to this work involving “usability testing” and an Expert Review component. The projects are indicated by site in the following table:

Status Report for Research Projects Supported by the DoD Collaborative

Project	Joslin	Hawaii	WRAMC	VA Boston	Status
An Assessment of the Test-Retest Reliability of the CDMP BAT	√	√	√	√	Recruitment complete at Joslin and VA; in recruitment at WRAMC; abstract submitted to CDC conference on Joslin results
An Assessment of the Validity of the CDMP BAT	√	√	√		In recruitment at Joslin
Digital Photography and Group Discussion as a Means of Affecting Dietary Change among People with Type 2 Diabetes: Feasibility Project	√				In recruitment
CDMP: Usability and Impact of the Workflow on Diabetes Care Specialists and on their Process and Quality Measures			√		Recruitment started; nearly finished
Prospective Multi-center Clinical Outcomes Efficacy and Cost Efficiency Study Using the JVN CDMP			√		Due to Appropriation budget reductions this study is to be initiated only at WRAMC
Prospective Multi-center Economic Analysis of the JVN Telehealth Eye Care Module		√	√		In recruitment started at WRAMC
Internet-based Diabetes Education and Case Management				√	Recruitment complete; all subjects will have completed 12-mos. intervention by May of 2007
Prospective Risk Benefit Analysis of the JVN Telehealth Eye Care Module	√			√	Protocol has been approved by the IRB at the VA and we are awaiting the HSRRB
Additional Human Factors Study for the CDMP Application: Expert Review of the CDMP	NA	NA	NA	NA	Completed
Additional Human Factors Study for the CDMP Application: Usability Testing of the CDMP	√				Completed; preparing manuscript for publication

Participating Site: Joslin Diabetes Center Study Summary

An Assessment of the Test-Retest Reliability of the CDMP BAT

The BAT is a new, stand-alone screening questionnaire within the CDMP that contains questions about psychosocial factors, nutrition, physical activity, alcohol and tobacco use, medications, general health, self-monitoring of blood glucose and economic factors. Since the BAT is a new instrument, it is necessary to test its consistency across repeated administrations; i.e., test-retest reliability. The objectives of this study are, first, to determine the test-retest reliability of the BAT and, second, to examine whether the BAT's test-retest reliability is invariant across social-demographic groups, health groups, and sites participating in the study. This is a multi-site observational study with two measurements per study subject taking place 2 to 4 weeks apart. The study protocol involves recruiting 42 English-speaking adults from each site who have type 1 or 2 diabetes.

Participants complete a test to assess their executive/cognitive function, questions about their social-demographics, and the BAT. For each site, the data analyses will calculate the correlation between item responses to the two administrations of the BAT. Additionally, we will calculate mean item scores and then use one-way analysis of variance to examine differences in the means among social groups (e.g., by gender, by age, etc.). Lastly, we will combine data from all of the study sites and replicate the correlational analyses.

Status: The data collection for this study has been completed at Joslin. (See below for a status report for the other sites). We have submitted an abstract to the CDC diabetes conference to present the results from Joslin.

An Assessment of the Validity of the CDMP BAT

Similar to the reliability study (see above), this project is concerned with the measurement properties of the BAT; however, this study focuses on two types of criterion validity -- concurrent, and predictive validity. Concurrent validity is the correlation between a measure and an external criterion at the same point in time. Predictive validity is the correlation between a measure and an external future criterion. This is a multi-site observational study with three measurements per study participant taking place 6 months apart. We expect to recruit 75 participants from each site. Study participants will be asked to complete the BAT, provide physical data, and complete validated questionnaires and logs containing criterion questions. The validated questionnaires/logs include the following: seven-day food diaries, seven-day physical activity diaries, certain physical measures, medical records, the Short Form Health Survey Questionnaire (SF-36), an abbreviated, validated version of the Center for Epidemiologic Studies – Depression (CES-D) scale, the Social Provisions Scale (SPS), the Summary of Diabetes Self-care Activities Questionnaire – Revised (SDSCA-Revised), and several questions used in clinical assessment and/or other surveys but that are not part of scales. For the analysis of concurrent validity, we will correlate responses to items from the BAT with responses to items from corresponding questionnaires, logs, physical data, and medical record data obtained at approximately the same time. Predictive validity will be evaluated by correlational analysis and regressing (in multiple regression models) health factors on scores from the sub-sections of the BAT and (where appropriate) responses to individual BAT questions completed at previous observations.

Status: This study is recruiting subjects at Joslin.

Digital Photography and Group Discussion as a Means of Affecting Dietary Change among People with Type 2 Diabetes: Feasibility Project

The purpose of this study is to test the feasibility of a new approach to diabetes nutrition care involving digital food photography and facilitated group discussions of the digital photographs. The overall hypothesis regarding this new approach is that, by photographing all meals and snacks (i.e., keeping 'photo journals') and participating in discussions about the photographs with peers and a nutritionist, people with diabetes will become aware of their behaviors and develop concrete strategies to meet nutritional recommendations. The study design is that of a randomized controlled trial with two groups: one group will receive standard diabetes nutrition care; the other group will receive the new approach to diabetes nutrition care involving digital photography of meals and group discussion of the photographs (treatment group). The required sample size is 36 (18 in each group). All subjects complete study questionnaires and an A1cNOW Metrika test before the digital photography and discussion sessions begin and at least 1 month (or more) after the digital photography discussion sessions end. Baseline data will be evaluated using descriptive analyses. The hypotheses will be evaluated using standard comparison tests, such as two-sample t tests and ANOVA.

Status: This study is recruiting subjects at Joslin. Our experiences to date with this project have provided the foundation for development of a personal health application through a Robert Wood Johnson Foundation grant (to be awarded Dec. 1, 2006).

Additional Human Factors Study for the CDMP Application

Although we believe that the CDMP can improve the care- and self-management of diabetes, it was necessary and desirable to ensure that the human factors considerations – specifically the interface of the human and the machine/information system – has been fully optimized to make the system easy to use, easy to learn, easy to remember, efficient, and “user friendly.” Thus, we conducted (with the American Institutes for Research, or AIR) a two-phase human factors study. In Phase 1, AIR human factors specialists with extensive experience evaluating medical software and device usability reviewed the existing CDMP software system. They assessed the software’s user interface for consistency of style and navigation aids, the number of keystrokes to perform

frequent tasks, the time required to perform these tasks, and potential areas of ambiguity. In Phase 2, we conducted a usability laboratory study with health care providers. The participants, after providing informed consent, used the CDMP to perform tasks simulating actual patient encounters in the ambulatory setting. Participants were video- and/or audio-taped while using the system, and were administered a questionnaire afterwards to collect qualitative data regarding subjective impressions. These data were summarized, analyzed, and aggregated into a report that made specific recommendations regarding opportunities for improving the system's usability.

Status: All data collection for this study is complete. We presented results from Phase 2 in a poster at the annual meeting of the American Telemedicine Association (May 2006, San Diego) and were awarded a blue ribbon by peer-review. The title of the poster was "Human Factors Analysis: Joslin Vision Network Comprehensive Diabetes Management Program."

Participating Site: Jamaica Plain VAMC, Dr. Paul Conlin, PI.

There are three studies being conducted at VA Boston Healthcare System. One study is fully enrolled, with participants in follow-up. Another study is in the final stages of planning. The last study has completed data collection and data analyses are ongoing.

Internet-based diabetes education and case management

In patients with diabetes mellitus there is a direct relationship between hemoglobin A1c (HbA1c), blood pressure and health care utilization due to the frequent development of adverse clinical outcomes. In an attempt to address these high-risk, high-cost characteristics, many healthcare systems have employed care-management strategies to focus the care of such individuals. However, there are limited data on the efficacy of this approach and no data on its cost-effectiveness. In this study we are examining the efficacy and cost-effectiveness of two methods of patient education and care management – a model that involves face-to-face encounters and telephone contact and a model that involves web-based encounters. We are comparing these different care management interventions to a usual care (control) group that receives no care management but is provided with a notebook computer and Internet access (to control for web-access per se). Thus, this study examines the effects of (a) Internet access, (b) a traditional model of education and care management, and (c) web-based education and care management on HbA1c and blood pressure. We will also explore the cost-effectiveness of these various interventions.

The specific aims of this study are to test the hypotheses that self-management education and care management using traditional or Internet-based methods will-

1. Reduce blood pressure $\geq -10/-5$ mm Hg
2. Reduce HbA1c $\geq 1.0\%$

-when compared to usual care supplemented with computer use and Internet access in patients with elevated HbA1c ($\geq 8.5\%$) over a 12 month period.

This study employs a randomized, prospective, parallel group design involving patients with diabetes mellitus. Primary outcome measures include clinical data (e.g. HbA1c, blood pressure, quality of life questionnaires) and secondary outcome measures include economic data (e.g. costs of case management, medication usage, and number(s) of ER visits/hospitalizations during the study period). Over 12-months we will measure HbA1c, office BP, and scores on the Problem Areas in Diabetes (PAID) questionnaire.

Status: The study is fully enrolled, with 152 participants having been randomized. There are 72 participants still in active follow-up. No results are available at present.

Clinical and cost-effectiveness of screening for diabetic retinopathy using tele-ophthalmology

The benefit and economic impact of screening for diabetic retinopathy using a dilated fundus examination has been clearly demonstrated. However, adherence with regular eye care is less than optimal. New strategies have been developed to increase screening for diabetic retinopathy. One such approach employs digital retinal imaging, using store-and-forward technology (tele-retinal imaging). Tele-retinal imaging may identify diabetic retinopathy and possibly concomitant non-diabetic eye diseases, such as glaucoma and cataracts, but it may

not be sufficient by itself. Other non-invasive testing that matches components of the comprehensive eye exam (e.g. visual acuity, intra-ocular pressure) may be completed by a technician. These techniques may provide supplementary information to that gained of retinal imaging, increasing its diagnostic agreement to the level of an eye examination.

We hypothesize that tele-retinal imaging supplemented with a non-invasive eye care assessment (hereafter referred to as a Technology Assisted Ophthalmic [TAO] examination) in patients with diabetes can substitute for a complete eye examination with a dilated fundus evaluation.

Specific Aims 1 and 2:

To determine the accuracy and level of agreement of a TAO examination and a complete eye examination for (a) need for referral to an eye care professional for further evaluation, (b) level of diabetic retinopathy, and (c) other referable non-diabetic eye disease

1. At baseline
2. Prospectively over two years

Specific Aim 3: To perform a cost minimization analysis comparing the TAO examination to the complete eye examination based on appropriate referral for follow-up eye care.

The study involves a two-arm, open, parallel group design in which participants will have both a TAO exam and a complete eye exam. Results from the two exam modalities will be compared for level of agreement, sensitivity, specificity and predictive value for the following outcome measures: eye care referrals, level of diabetic retinopathy, and the presence of other referable non-diabetic ocular disease. A cost effectiveness analysis will also be completed.

The study will enroll 500 participants with high-risk characteristics to initially evaluate the baseline level of agreement of the TAO examination and a complete eye exam. This provides the best opportunity for assessing agreement in diagnosing all levels of diabetic retinopathy, non-diabetic ocular pathologies and referral for further eye care. Approximately 35-40% of these participants will require referral for eye care, based on findings from the initial examination. We will then follow the subset of individuals with no diabetic retinopathy or mild retinopathy (approximately 300 participants) with annual examinations (both TAO and complete eye exams) over a 2 year period to determine their level of agreement and the incidence of new retinopathy and/or non-diabetic eye disease. In this setting we will also assess the economic impact of tele-retinal imaging in comparison to a complete eye examination, using a cost-minimization approach.

Status: The study is in the final stages of development. It is fully approved by the IRB at the VA and we have submitted the protocol to the HSRRB. There are no findings to date.

An Assessment of the Test-Retest Reliability of the CDMP BAT

We present the summary for this study above, under the information for the Joslin Diabetes Center.

Status: We have completed data collection. Data analyses are ongoing.

Participating Site: Department of Defense, Walter Reed Army Medical Center, Dr. R. Vigersky, PI
Prospective Multi-center Cost Efficiency Study Using the JVN Telehealth Eye Care Module: A Prospective Economic Analysis of the Joslin Vision Network in Detecting Diabetic Retinopathy and Macula Edema

The goal of this study is to collect prospective data on incurred costs and observed outcomes that will be analyzed using a decision analytic model. A retrospective study upon which this prospective study is based has been published (Whited, J.D., Datta, S., Bursell, S-E., Aiello, L.M., Aiello, L.P., Cavallerano, J., Conlin, P.R., Horton, M., Vigersky, R.A., Poropatich, R.K., Challa, P., Darkins, A., "A Modeled Economic Analysis of the Joslin Vision Network as Used by Three Federal Healthcare Agencies for Detecting Proliferative Diabetic Retinopathy, Telemedicine and e-Health Journal 11: 641-651, 2005).

This prospective study has tremendous potential and importance and it will be a landmark evaluation for this type of technology. The following research questions will be answered:

1. What costs accrue when annual eye examinations in a diabetic cohort are performed by ophthalmologists or optometrists in conventional clinic-based settings compared with JVN examinations?
2. What is the cost-effectiveness of JVN examinations compared with clinic-based eye examinations for the detection and treatment of diabetic retinopathy and macular edema?
3. What are the aggregate costs and outcomes, regardless of specific diagnoses or treatment options, when annual eye examinations are performed with the JVN compared to clinic-based eye examinations based on a cost-consequence analysis?
4. What are the potential time-dependent changes in self-reported vision-related daily functioning and well-being (i.e., "quality of life") of patients managed by the JVN compared to patients managed by conventional clinic-based care?

Status: After a lengthy IRB approval process and changes in key study personnel, issues around camera connectivity, and the training of new readers, the study is currently in recruitment. To date, 60 patients have been screened, and of these 25 subjects have been consented and randomized. The study recruitment goal is 243 patients

The Sensitivity and Specificity of Stereoscopic Non-mydratic Digital Retinal Photography in Detecting Diabetic Retinopathy

The purpose of this study is to validate the sensitivity and specificity of the JVN Telehealth Eye Care System within a secure environment of a military healthcare network.

Status: We reviewed the records of 244 patients with diabetes who had a dilated fundus exam (DFE) and nonmydratic digital stereoscopic retinal imaging (NMDSRI) done contemporaneously at four locations in the metropolitan Washington, DC area. There were 314 gradable images. There was an 86% exact agreement in the grading between NMDSRI and DFE; 227 eyes with no DR and 40 eyes with DR. In 46 eyes there was a disagreement between the grading made by the two techniques. NMDSRI detected DR in 35 eyes reported as normal by DFE and in the remaining 11 eyes the DFE was one grade higher than NMDSRI. Adjudicated non-concordant exams were within 1 grade. In the 76 eyes with DR, retinal thickness could not be assessed in 17. When the NMDSRI was gradable, the overall sensitivity of NMDSRI was 98% and the specificity was 100% for retinopathy within one grade of the dilated fundus examination. In the limited number of eyes that had DR with macular edema (6), there was 100% agreement with the clinical exam. We concluded that NMDSRI is a sensitive and specific method for screening and diagnosis of diabetic retinopathy in a secure military healthcare environment. It may lead to significant cost savings if used in place of dilated fundus exams for routine yearly screening and may help improve compliance with the standards of eye care for patients with DM among military healthcare beneficiaries.

This study has been presented at a national meeting and recently published in the October issue of Diabetes Care.

- Ahmed, J., Ward, T., and Vigersky, R.A. "Diabetic Retinopathy Screening Using Telemedicine," 3rd Annual Diabetes Technology and Therapeutics Society Meeting, San Francisco, CA, November 2003.
- Ahmed, J., Ward, T.P., Bursell, S-E., Aiello, L.M., Cavallerano, J.D., and Vigersky, R.A., "The Sensitivity and Specificity of Non-Mydratic Digital Stereoscopic Retinal Imaging in Detecting Diabetic Retinopathy." Diabetes Care 29: 2205-2209, 2006.

The Usability and Workflow Impact on Diabetes Care Specialists of the Comprehensive Diabetes Management Program (CDMP).

This project will examine the usability and impact on clinical workflow of a new health information technology (HIT): a web-based Comprehensive Diabetes Management Program (CDMP). The CDMP is a new, interactive, web-based tool for physicians, care managers and people with diabetes. The project will examine the CDMP's usability and impact on clinical workflow by comparing them to those of the existing, baseline HIT system in the Walter Reed Army Health Care System (WRHCS). Specifically, we will examine the Diabetes HealthCard data (which documents the process and quality measures of the Diabetes Quality Improvement Program

(DQIP)) of selected diabetes health care providers and administer questionnaires regarding aspects of the diabetes care system before and after adoption of the CDMP. In addition, we will evaluate the use of the CDMP by observing the interactions of these care providers with standardized patients (i.e., actors who have been trained to provide a realistic initial or follow-up history for a simulated patient). Finally, we will use structured focus group discussions with the providers lead by a trained, experienced facilitator. Health care providers selected for this study will be the Nurse Practitioners (NPs) of the Diabetes Institute of the WRHCS, all of whom have participated in developing the CDMP over the past two years.

Status:

- The study protocol has been reviewed and approved by all appropriate IRB's.
- The nurse practitioners in the Diabetes Institute have been trained on the CDMP and consent for their participation in this study has been obtained.
- The study was initiated in June 2006 and data are being collected for analysis.
- The results from the CDMP usability and clinical workflow analyses will be incorporated into a revised version of the CDMP and into the manual of operations for the different proposed studies using the CDMP. In this case the proposed multicenter study described below will only be initiated after completion and code rewrite of the CDMP usability and workflow study.

Prospective multi-center clinical outcomes efficacy and cost efficiency study using the JVN Telehealth Comprehensive Diabetes Management Program: Improving Outcomes in Patients with Type 1 and 2 Diabetes by Using a Comprehensive Diabetes Management Program (CDMP) in the Primary Care Clinics of the Participating Agencies and the Joslin Diabetes Center

The goal of this study is to determine whether or not the use of information technology by primary care physicians in the Walter Reed Health Care System (WRHCS) and other participating agencies and institutions can improve outcomes in patients with both type 1 and type 2 diabetes mellitus. The WRHCS is an integrated population-based primary and specialty military health care provider for active duty service members, families and retirees in the National Capital area. The specific aims of this study are to determine:

- 1) The efficacy, safety, and acceptance of a comprehensive diabetes management program (CDMP) enhanced by a computer assisted decision support system (CADS) which will analyze blood glucose data and provide recommendations for management in improving outcomes in patients with diabetes mellitus when utilized by primary care providers (PCPs) including general internists, family practitioners, nurse practitioners, and physicians assistants.
- 2) Whether or not further improvement in glycemic control can be obtained by providing primary care providers and their patients with a web-based blood glucose data monitoring and analysis (GDMA) system with some providers having access to CADS which will provide an automated interpretation of their patients' glucose profile and recommendations for therapy (either insulin dose adjustment or alteration in oral medication).

We will determine:

- a. whether clinically and statistically significant improvement in glycemic control can be sustained for up to 3 years;
- b. whether there is a decrease in the number of major and minor hypoglycemic episodes, emergency room visits for diabetes-related causes, and hospitalizations and hospital days for diabetes-related illnesses
- c. whether or not there is improved adherence to generally accepted clinical practice guidelines
- d. whether there is an improved quality of life for patients with diabetes mellitus

We will compare patients whose providers are using CDMP + GDMA with those receiving "usual care" by these same providers. Patient-related parameters that will be examined include Hemoglobin A_{1c}, mean (+/- std. dev. and +/- SEM) blood glucose values, the total number of office visits and telephone consultations/e-mails, and compliance with scheduled office visits, laboratory testing, and with medication and treatment regimens. Similarly, we will analyze the compliance with the Diabetes Quality Improvement Project (DQIP - a set of minimum criteria for performance reporting of diabetes care¹) and the adherence to the clinical practice guidelines of the DoD/VHA, American Diabetes Association (ADA), and American Association of Clinical Endocrinologists (AACE) in physicians who have or have not had the access to CDMP or CDMP + GDMA with those providing "usual care".

Dissemination and Sustainability: If the present project demonstrates improved quality of care and clinical outcomes for patients with diabetes mellitus, the use of this approach will be sustained within the WRHCS for patients followed by primary care providers as well as those followed by endocrine/diabetes specialists and sub-specialty nurse practitioners. We estimate that this would affect approximately 6,000 patients with diabetes. The expenditures for such a roll-out in routine practice would be justified on the basis of the present study, if the results indicate that the approach improves quality of care. If use of algorithms for interpretation of the glucose profile results in improved quality of care, then all primary care providers would be given the software, and it would also be made available to endocrine/diabetes specialists. If the present results indicate improvement in clinical outcomes in some categories of subjects but not others, the present system would be modified.

In view of the costs of complications of diabetes, if the present results demonstrate that the CDMP (with or without GDMA) results in improved quality of care, then the Principal Investigator will be in position to advise the U.S. Army Surgeon General to disseminate similar programs to all Army treatment facilities. The number of individuals who might be covered in such a “roll-out” could be expected to number conservatively above 50,000. We would submit the results of the present study for publication in a major peer reviewed journal. We would provide all necessary information for individuals, groups or health care systems to initiate similar programs at their facilities, and make recommendations about the most efficient manner for monitoring the impact of the program.

Status:

- The Department of Defense has introduced a new electronic medical record – AHLTA (previously known as CHCS2). In order to make CDMP useful for providers, it will have to be incorporated into AHLTA so that it does not represent a “stovepipe” application outside the enterprise solution. We are in the process of testing the ability to integrate CDMP into AHLTA by conducting a “proof-of-concept” study that will investigate the feasibility of integrating CDMP’s Diabetes Assessment Tool Kit (DATK) into AHLTA. The DATK is composed of the Behavior Assessment Tool (BAT), the Nutrition Assessment Tool (NAT), and a Risk Stratification Algorithm (RSA). We plan to assess the reliability of the DATK to provide accurate information when accessed on-line versus a computer in the clinic and to assess whether or not tools and algorithms outside the CHCS2 domain can provide “alerts” inside the domain
- CADS development began in 2005 with initial focus groups including primary care providers who reviewed the algorithms and sample cases. The software development for CADS has now been completed and testing its accuracy is underway using sample cases drawn from the Diabetes Institute records. Preparation for integration into CDMP and CHCS II has begun.
- Study protocol and Manual of Operations will be written contingent on results from the above usability study (see #3 above).

An Assessment of the Test-Retest Reliability of the CDMP BAT

The summary for this study is presented in the Joslin section above.

Status: This study is now approved by all relevant IRB’s. Up to 42 patients have been approved for this study at WRAMC; 32 patients have volunteered to be participants and are in the process of being screened for eligibility.

An Assessment of the Validity of the CDMP BAT

The summary for this study is presented in the Joslin section above.

Status: This study will be submitted for review by the IRBs at WRAMC shortly.

Development and validation of Learning Level Assessment and Readiness to Learn tools for the JVN Telehealth CDMP application

This effort was identified as the first phase in developing a tool for patient knowledge assessment in the CDMP. The CDMP identified learning level assessment and readiness to learn as critical capabilities for enhancement of the CDMP application. It was recognized that there were only a few studies that addressed these issues and that the ability to perform rigorous studies to assess learning levels was of high value for this program.

The only validated tool for learning level assessment is the Rapid Estimate of Adult Literacy in Medicine (REALM) (1). This tool was developed as a rapid screening device to assist physicians in identifying patients with limited reading skills and in estimating patient reading levels. The results from this study suggest that the use of REAL appears to be a practical instrument for estimating patient literacy in the arenas of primary care, patient education and medical research. Another study used the Wide Range Achievement Test (WRAT) for measuring reading ability and spelling (2). Study results found that the better the ability to read and spell the better the accuracy of recall for food intake.

The limited studies currently available that address this issue provide the rationale and value for the development of a Learning Level Assessment tool for the CDMP. Concomitant with learning level assessment there also needs to be the ability to assess the patient's readiness to learn. Clearly if the patient has no interest in learning then the level of learning ability will be of little value.

The CDMP working group will develop a learning assessment tool based on the current validated measures and the available expertise within this group in the behavioral sciences will provide a valuable tool for assessing the patient's willingness to learn. This effort will be unique and will provide a significant advance in diabetes behavior modification.

Upon completion of this tool, it will need to be validated in a study comparable to that designed for the BAT above.

Status: Development of the appropriate tools that meet the different user requirements have been completed.

Deployment of JVN Telehealth CDMP application into the Department of Defense Electronic Medical Record

The overall objective of this study is to incorporate CDMP and related applications into the enterprise electronic medical record (AHLTA). We have three specific objectives: Objective 1 is to conduct a "proof-of-concept" study that will investigate the feasibility of integrating CDMP's Diabetes Assessment Tool Kit (DATK) into AHLTA (see above) Objective 2 will evaluate multiple methods of viewing and integrating glucose meter data uploaded through CDMP's Diabetes Mellitus Everywhere (DME) into AHLTA. Once in the CDMP application database the glucose data can be viewed in either the presentation-rich web-based environment of CDMP or in a PureEdge form. We can then incorporate the data into an AHLTA encounter via standard cut-and-paste techniques from CDMP or through the use of PureEdge forms. In the case of PureEdge forms, we will use the planned capabilities of the product to import data into AHLTA automatically. Objective 3 is to assess the reliability of the glucose data to provide accurate information when accessed on-line via DME versus a computer in the clinic using proprietary software.

Status:

- As noted above, the Department of Defense has implemented a new electronic medical record (AHLTA) to replace HealtheForces. Deployment of CDMP into HealtheForces at Walter Reed Army Medical Center (WRAMC) was completed in May 2005 but while data is still available for analysis, no new data is being entered into that system. We had initially trained the Diabetes Institute staff at WRAMC in using CDMP in June 2005. However, re-training had to occur in May 2006 so that CDMP could be used in a preliminary way with AHLTA.
- We have begun to integrate the DATK (and plan to integrate the tabular and graphic data which are uploaded from patients' glucose meters into DME) into AHLTA. There is no similar functionality in AHLTA.

Participating Site: University of Hawaii Dr. D Peters, PI.

Deployment of JVN Telehealth CDMP application into community health centers in Hawaii

The major goals of this continuing project are the establishment of a telemedicine system for comprehensive diabetes management and the assessment of diabetic retinopathy that provides increased access for diabetic patients to appropriate care, that centralizes the patients in the care process, that empowers the patient to

better manage their disease, that can be performed in a cost effective manner, and that maintains the high standard of care required for the appropriate management of diabetic patients. The aim of this program of research will be to perform the appropriate clinical validation, cost efficiency, and risk benefit studies associated with the use of the recently developed Comprehensive Diabetes Management Program (CDMP) and the Joslin Vision Network (JVN) Eye Health Care Program that is now a module of the CDMP. These research studies and the implementation of CDMP were originally planned at Tripler Army Medical Center (TAMC) in Honolulu, HI. Because the decision was made at TAMC to accelerate the adoption of a new electronic medical record (AHLTA), implementation of the CDMP was delayed indefinitely. Consequently, alternative sites in community health centers were chosen for these research studies and the implementation of the CDMP. Waianae Coast Community Health Center, Waianae, HI; The Physicians Center at Mililani, Mililani, HI; and the Molokai General Hospital, Kaunakakai, HI.

Status:

- Three community health centers were identified that agreed to participate in the proposed research studies. The community health centers are: Waianae Coast Community Health Center (WCCHC), Waianae, HI; The Physicians Center at Mililani (PCM), Mililani, HI; and the Molokai General Hospital (MGH), Kaunakakai, HI. Subcontracts were let with the Waianae Coast Comprehensive Health Center (April 2006) and Molokai General Hospital (April 2006) to fund CDMP and JVN implementation and ongoing associated personnel costs. Alternative methods for funding the Physician Center at Mililani were identified. Personnel have been hired directly through the Research Corporation of Hawaii (RCUH) for this project.
- A subcontract was let with Estenda Solutions, Inc. to provide technical support for the JVN and CDMP installations and maintenance.
- Kari-Jo Coll was hired through RCUH to serve as the JVN retinal image reader for studies done at the three community health centers. A reading station was set up for her in San Jose, CA. Dr. Paula Katalinic will serve as the back-up reader. A reading station has been set up for her in Australia.

JVN Imaging Cameras and Acquisition Stations were installed in each of the three community health centers (February 13 -17, 2006). Additional installation issues were resolved and VPN connections were established. Two staff members were identified for JVN imager training: Darlene Kaahaaina from Waianae Coast Comprehensive Health Center and Radmila Esteron from Molokai General Hospital. Ms. Kaahaaina will also do the JVN imaging for the Physician's Center at Mililani. Both imagers, as well as, Frederick Walsh from Estenda Solutions completed imager training at the Joslin Diabetes Center, Boston, MA, February 27 – March 1, 2006. As of September 2006, 181 patients have been imaged at the three centers.

- The CDMP has been installed at the Physician Center at Mililani and Molokai General Hospital. Given that neither of these centers has an electronic medical record, patients' past two-year medical history must be extracted from charts. This has been initiated and is on-going. Meetings have been held with personnel from Waianae Coast Comprehensive Medical Center to finalize the implementation of the CDMP. Frederick Walsh, Estenda Solutions, is developing the interface for the CDMP with the WCCHC electronic medical record, NextGen.
- Frederick Walsh, Estenda Solutions, and Joseph Humphry, MD, have worked with the two major laboratories in the state, Diagnostic Laboratory Service, Inc. and Clinical Laboratories of Hawaii, LLP, on the transfer of clinical laboratory data into the CDMP. The Data Transfer Agreement has been signed by the Physician Center at Mililani. The Data Transfer Agreements are under review by the Waianae Coast Comprehensive Health Center and Molokai General Hospital. The programming code for the transfer of laboratory data was written and is currently under QA review by Estenda Solutions.

An Assessment of the Test-Retest Reliability of the CDMP BAT and An Assessment of the Validity of the CDMP BAT

Please refer to the section on Joslin for a brief description of both studies.

Status:

- All three community health centers, Waianae Coast Comprehensive Health Center (WCCHC), the Physician Center at Mililani (PCM), and Molokai General Hospital (MGH), have reviewed

descriptions of the Behavioral Assessment Tool Reliability and Validity studies. All three sites have agreed to conduct the studies.

- The protocol entitled “An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program’s (CDMP) Behavioral Assessment Tool” was written for the Physician Center at Mililani. The protocol was submitted to the University of Hawaii Committee for Human Studies. It was approved on September 21, 2006. The protocol was also submitted for review to the ORP Human Subjects Research Review Board (USA MRMC). The review was received October 11, 2006. The protocol is currently being revised and prepared for resubmission.

Development of additional modules for the JVN Telehealth CDMP application

The objectives of this study are to develop additional modules that are enhancements to the existing CDMP application. Additional modules will include a medication module, an outcomes and reporting module, an education scheduling and tracking tool, a knowledge assessment tool, a nutrition module, a patient portal module, integration of wireless home monitoring devices, and a primary care practitioner module.

Status: Joseph Humphry, MD, designed a module for incorporation into the CDMP for use by health care providers for recording and displaying patients’ medications. Frederick Walsh developed a prototype of the module for review by members of the consortium.

Durham VAMC/Duke University Medical Center SubContract, Dr John Whited, PI

Prospective Economic Analysis of the Joslin Vision Network (JVN) Telehealth Eye Care Module

Status:

The role investigators play at the Durham VAMC and the Duke University Medical Center in this protocol is study design and data analysis. This site was largely responsible for the study design and protocol development. In addition, the statistical support for this project resides at this site. Our site will be responsible for receipt of the data and data analysis. The health economist assigned to this project is at this site and will be responsible for the economic data output and results that are derived from this study.

The following goals have been achieved during the review period:

- IRB approval. We have received initial IRB approval for this project at the Durham VAMC and Duke University Medical Center IRBs. Initial approval from the Durham VAMC was received on July 21, 2006. Initial approval was received from the Duke University Medical Center on June 29, 2006. Dual site approval was necessary since study funds are disbursed at both sites and researchers for this study are based at both sites. Approval for annual continuation review will be sought and obtained when appropriate.
- Study team. The study team has been assembled and has had preliminary meetings in anticipation of receipt of study-related data. The study team consists of John D. Whited, MD, MHS (site PI), Santanu K. Datta, PhD, MBA (health economist), Steven C. Grambow, PhD (supervising statistician), and Amy Jeffreys, MStat (statistician).
- Project management plans. The study team has reviewed the protocol, data collection methods, data analysis plans, and data transmission methods. We have also discussed the web-based interface proposed for use as a means of data transmission. The Health Services Research and Development Service has experience and local expertise with the use of web-based interfaces for data collection and transmission. Once study enrollment commences and we begin to receive study data, the study team will schedule regular meetings to review the progress of the study. Study and data management will be conducted using the Standard Operating Procedures of the Durham VAMC Health Services Research and Development Service. This includes measures to protect the privacy and confidentiality of research data and personal health information.

The analytic plan is as described in the final IRB-approved study protocol. No changes to the protocol are anticipated. However, if any changes are necessary, the site researchers will work with the collaborating institutions to amend the protocol and seek IRB approval for the changes.

Joslin Diabetes Center Research and Development Status Reports

The above section addressed the research components of this large collaborative effort. In the following section, we summarize key issues and milestones in the research and development component of this grant.

CDMP Development

To review, the CDMP is a two-part application developed for medical centers and clinics.

The first part of the application -- the CDMP Core (the Provider Portal) -- is a web-based, secure, one-stop, customizable, non-proprietary clinical tool that considers the whole patient and embraces Wagner's components for patient-centered chronic care. CDMP's primary users are

- Care managers who facilitate interactions between patients
- CareTeam (physicians, nurses, educators, exercise physiologists, nutritionists, and behavioral clinicians)
- Providers without specialization in diabetes

The second part of the application -- the Patient Portal (currently called DME) -- is also web-based and secure. It is a set of tools for self-management and communication that provides:

- A current health profile that reflects CDMP data in patient language
- The ability to upload, review, and share (with a designated provider) personal health data from one or more monitoring devices
- An evolving patient-centered collection of health histories, articles, plans and suggestions designed for that patient and his/her support system.

Usability Study. The recently completed Usability study of the CDMP application has been completed and the results were presented at the recent American Telemedicine Association Conference in San Diego (See Appendix 4 for the poster presentation). A number of proposed modifications to CDMP were identified from this study and are enumerated below (the status of each modification is indicated with respect to implementation within CDMP).

1. Patient Menu

- a. Change Patient Home menu option to Patient Snapshot. Make this the default page when viewing a patient. Add a menu option for Alerts/Reminders. (multiple changes will be made to inform the user of new alerts/reminders. See below under snapshot). **Status:** Implemented in CDMP
- b. Add menu option under Patient Snapshot for Alerts/Reminders. **Status:** Not Done, Patient Home link still on patient menu to go to alerts/reminders
- c. Change Education and Education Assessment menu options. **Status:** Implemented in CDMP
 - i. Change the word Assessment to Evaluation. **Status:** Implemented in CDMP
 - ii. Change/regroup menu options related to Education and Education Assessment. **Status:** Implemented in CDMP

Change From this	To this...
Education	Education
Ed Assessment	- Assigned
- New	- Add/Edit Evaluation
- History	- Evaluation History

- d. In places where menu options just expand the menu when clicked, we will create a page that displays the submenu options. For example, when the user clicks Clinical, the menu will expand as it does now, but also display a page listing the menu options underneath Clinical. Each menu option will be listed with a description of that page. The menu options can be clicked on that page or in the menu. **Status:** This feature will be implemented in the next CDMP software release

2. Snapshot – will be done in conjunction with 1 patient menu changes

- a. Enhance information related to alerts in top left panel to make new alerts more clear. **Status:** Implemented in CDMP
- b. Add information in top left panel about reminders due. **Status:** Implemented in CDMP

- c. Add “alert message” in header similar to home page notification of new messages or SMBG or SMBP data to notify user of new alerts. **Status:** It was determined that this was not necessary...alert is on Care Team Home not on patient level, future enhancement to add patient level alerts
 - d. Add printer-friendly functionality. **Status:** Implemented in CDMP
- 3. Care Plan
 - a. Action Items/Reminders Tab
 - i. Change Action Item Tab name to Reminders. Status: Implemented in CDMP
 - ii. Change “Close” to “Done” (or “Completed” – see above). **Status:** Implemented in CDMP
 - iii. Move Add Action Item Button on Reminder tab to top of tab so it is easily seen. **Status:** Implemented in CDMP
 - iv. In Assigned To drop down – change the patient entry to the actual patient’s name. **Status:** Implemented in CDMP
 - v. Create Action Item/Reminder Categories for organizational purposes. **Status:** Implemented in CDMP
 - b. Save/Cancel button – the save/cancel button should always be visible on this page – either add to bottom or modify page so top buttons are always visible. **Status:** Implemented in CDMP
 - c. Close Process
 - i. Actual End Date goes away **Status:** Implemented in CDMP
 - ii. Care Plan automatically closes when planned end date passes [close checkbox is used]
 - iii. When user clicks add/edit **Status:** Implemented in CDMP
 - 1. if a care plan exists and is open, display current care plan
 - 2. if care plan exists, but is closed, a new blank care plan will be created
 - a. Future versions will allow you to copy the old to the new.
 - 3. If no care plan exists, create a blank care plan.
 - d. Remove the Physical Tab **Status:** Implemented in CDMP
- 4. Alerts
 - a. Modify the Alert Close Process [enhancement was to add buttons to allow the user to add an action and close the alert in one step] **Status:** Implemented in CDMP
 - i. Change “Close” to “Delete”
 - ii. No Action Item is required.
 - iii. When Delete is selected, display a popup confirmation message to make sure they really want to delete the alerts.
 - b. Add a mouse over on the filtering to explain what it does. [changed filter link to explicit “ON” and “OFF” option buttons] **Status:** Implemented in CDMP
- 5. Education Assessment (Now Evaluation)
 - a. Modify text on page to reflect change to “Evaluation” **Status:** Implemented in CDMP
 - b. Change method used to select subcategories. **Status:** The features below will be implemented in the next CDMP software release
 - i. Remove existing drop down, link, and display
 - ii. Add one link “Add/Edit Target Areas”, when clicked
 - 1. DHTML list of available options are displayed
 - 2. User can select multiple by selecting checkboxes.
 - 3. user clicks Save/Cancel
 - 4. DHTML window closes
 - iii. Selected Target Areas are display in list on right hand side
 - 1. Next to each item, display a delete icon. If clicked, delete the item. No confirmation required.
- 6. Reminders
 - a. Change “Close” to “Done”. **Status:** This feature will be implemented in the next CDMP software release
 - i. Open Item: Is “done” the best? What about “completed”?
 - b. Drop Reminder Category. **Status:** This feature will be implemented in the next CDMP software release
 - c. Display assigned by as right most column – this is the created by column **Status:** This feature will be implemented in the next CDMP software release

- d. When viewing Patient reminders – remove ability to filter – always display all reminders **Status:** This feature will be implemented in the next CDMP software release

7. Miscellaneous

- a. On all panels where data is sorted. **Status:** The features noted below will be implemented in the next CDMP software release
 - i. Display an arrow next to the column header indicating the direction the data is sorted.
 - ii. This sort indicator should be displayed on initial page retrieval.
- b. Update Data Changed Message – “Press OK to discard changes and leave this page. Press Cancel to stay on the current page.” **Status:** This feature will be implemented in the next CDMP software release
- c. JVN Eye Diagram – add text “Click on R/L links or image list to see eye images” **Status:** Implemented in CDMP
- d. Graphs – on y-axis – rotate dates so they are easier to read – should be displayed horizontally. **Status:** This feature will be implemented in the next CDMP software release
- e. Clinical Data Listings (Labs, Medications, Procedures, Diagnoses) **Status:** The features noted below will be implemented in the next CDMP software release
 - i. Add alphabet across top, clicking on letter filters list based on the letter selected.
 - ii. Have “all” option to return to base – have tooltip when user mouses over all to explain this.

Other research and development initiatives associated with the CDMP have involved: partnering with iMetrikus, developing new modules to expand the capabilities of the application, and working group meetings to confirm functionality and identify additional functional enhancements.

Partnership with iMetrikus. As the patient portal began to be used by more and more patients to track critical aspects of their health and upload their meter data, we began to see an increase in the time our technical team and Estenda Solutions spent interpreting data, and documenting and supervising operating procedures for a variety of glucose meters. In order to efficiently provide functionality for increasing numbers of physiological home monitoring devices CDMP development initiated a partnership with iMetrikus, who provide a large number of device adapters and a universal data interface to the CDMP data server, both allowed us to branch out to other disease states and types of devices and frees the technical development team to focus on other more critical CDMP development efforts.

iMetrikus currently supports some 30 devices – blood glucose, blood pressure, weight scales, and oximeters, with more in the pipeline every day. The MetrikLink adapters convert the data into a single format for delivery to the MediCompass hub. CDMP takes the data handoff directly. iMetrikus is currently working with us to support several devices types within the same clinical program.





Nutrition Module. A CDMP working group has put together several basic tenets of meal planning and nutrition information for patients and providers and is now working to find supporting web-based materials available for online work and/or printing for handouts. The CDMP web-based education list now includes most of the vetted sites the working group found valuable. The working group is also looking to find a new way to present this information to patients with limited general and health literacy.

Medications Module. Medications are an increasingly important topic in the discourse on patient safety and personal health records. The CDMP Consortium, therefore, has determined that it is necessary to develop a state-of-the-art medications module.

Discussions on medications have led to several iterations for Consortium consideration. Questions were:

- Do we present both disease state-specific – diabetes, in this instance - meds related and general meds?
- About off the shelf medications and supplements, should they be included?
- How much real estate is available for medication categories?
- How far back should the medications tracking go for presentation?
- If EMR doesn't include all meds, how are they added?
- If EMR doesn't include a pharmacy module, how to track filled scripts?
- How to consider medication or supplement self-reports?

Below is the latest form for medication presentation in CDMP.

Date	Name	Dosage	Frequency	Last Filled	Notes	
06/01/2006	METFORMIN HCL	1000 mg	qd		This is a test	
05/13/2006	ACTOS	30	q am			
04/07/2006	GLIPIZIDE	5	2 Times per Day	04/07/2006		
03/09/2006	A.S.A.	1	as directed	03/09/2006		
07/07/2005	ACETAMINOPHEN	20-12.5MG	bid			
04/17/2005	PRINZIDE	20-12.5MG	bid			
09/13/2004	TERAZOSIN HCL	2MG	q hs			
09/13/2004	SYNTHROID	125MCG	qd			
09/13/2004	HUMALOG	100U/ML	as directed			
09/13/2004	ONE TOUCH ULTRA - STRIPS	STRIPS	as directed			
09/13/2004	BD Ultra-Fine - Syringes	29G 1CC	as directed			
09/13/2004	HUMULIN N	100U/ML	as directed			
09/13/2004	ZESTORETIC	20-12.5MG	qd			
09/13/2004	FUROSEMIDE	40MG	q am			
06/13/2004	ZESTORETIC	20-12.5MG	qd			
06/05/2004	ONE TOUCH ULTRA SOFT - LANCETS	LANCET	prn			
06/05/2004	ONE TOUCH ULTRA - STRIPS	STRIPS	N/A			
06/05/2004	ZESTRIL	20MG	bid			
06/05/2004	FUROSEMIDE	40MG	q am			
06/05/2004	ONE TOUCH ULTRA - STRIPS	STRIPS	as directed			
06/05/2004	SYNTHROID	125MCG	qd			
06/05/2004	TERAZOSIN HCL	2MG	q hs			
01/03/2003	ONE TOUCH PENLET LANCET	LANCET	as directed			
01/03/2003	ONE TOUCH MONITORING - STRIPS	STRIPS	as directed			
01/03/2003	BD Ultra-Fine - Syringes	29G 1CC	as directed			
01/03/2003	HUMULIN R	100U/ML	as directed			
01/03/2003	HUMULIN N	100U/ML	as directed			
01/03/2003	SYNTHROID	125MCG	qd			
01/03/2003	FUROSEMIDE	40MG	q am			
01/03/2003	ZESTRIL	20MG	bid			

Mental Health Module. The Consortium recognizes the important, reciprocal relationship between diabetes and poor affective functioning, such as depression. Care management tools may mitigate the relationship. See, for example, the attached paper authored by Fonda and colleagues and currently under review, "The Relationship of Internet-based Care Management and Changes in Glycemic Control to Depressive Symptoms and Diabetes-Related Distress." Thus, the Consortium is deepening the mental assessment and decision-support tools within the CDMP. The goal of these tools will be to identify depression and giving providers guidelines to handle the outcome. How to refer, who are first line providers, etc. are clinic specific issues that affect workflow. As with the basic nutrition assessment tool, such tools will include a scoring script – "If this, then this." to facilitate mental health care delivery – often a presence with patients already coping with diabetes, CHF, etc.

Training tools.

Our CDMP Usability work with AIR and direct work with CDMP users changed some of our approach to training CDMP users. Traditional training involves taking the user logically through the application and covers keystrokes and trouble shooting. FAQs, and online Help provide local support. We created a new way to use CDMP. Functions are grouped as they are often used – at least in the beginning – as

- Reference tools
- Assessment tools
- Communications tools
- Collaboration tools
- Survey tools

Some of our current CDMP users find this annotated-screen, paper-based, spiral-bound booklet sits at the computer with them. They can stay focused on the work they are doing without having to open other windows to find help.

CDMP Summit Summary. The CDMP Consortium – comprised of Joslin, JVN TeleHealth, DOD, VA, IHS, CDC, CHCs, and specialized academic researchers – meets twice a year with the overall goal to share technical, clinical, and behavioral updates to the CDMP Core application, JVN imaging and reporting tool, the patient portal, survey tools, and the study management tool. Most of our members are part of ongoing studies and working groups. This meeting allows us to share research, and related software and hardware development coming out of our clinical and behavioral work. We call these meetings “Summits”.

Each Summit we try to include speakers with complementary and related research, products and programs. Moving the Summit to different locations gives us access to local clinics and clinicians who do what we do. They are always receptive to sharing some of their work with us resulting in productive question and answer sessions.

Last winter’s Summit, we heard from several researchers (several of whom are longstanding members of the Consortium) who are developing tools that may be appropriate for incorporation into the CDMP. Specifically, we heard from Kate Lorig, founder and director of the Patient Education Research Center at Stanford University. She has developed peer education programs that let patients with similar needs talk to each other, led by a patient trained in the Center’s methodology. Another Stanford researcher, Mary Goldstein, presented her work with hypertension. She has developed a decision matrix to guide clinicians through the web of HTN treatment. Dr Dale Vincent (a member of the Hawaii team) presented on the value of group visits and how CDMP could be used to facilitate this process. Dr. Jamie Rosenzweig from Joslin is working on a Doctor’s Quality Project looking at currently accepted diabetes care measures, where they come from, about the National Diabetes Quality Improvement Alliance standards, and public reporting.

This summer’s Summit offered a wide spectrum of disease management topics and experiences. To summarize, the VA investigators presented their experiences using the CDMP in their research study described above. Dr. Lloyd M. Aiello and Marc Van Marter, a senior JVN developer, presented what’s new and forthcoming with the JVN eye care program. Dr. Vigersky presented on the decision matrix of a new tool providing clinical decision support tool for health care practitioners who care for people with diabetes. Additionally, Dr. Susan Oliverio, an internist on the staff of the Neighborhood Health Plan in Boston, presented her work on an interactive program called “Thumbs Up for Healthy Choices” for kids and adolescents. Dr. Stephanie Fonda and Judy Phillips presented aspects of the digital photography and nutrition study summarized above. Dr. Dale Vincent led a discussion about the use of cell phones, specifically SMS text messaging, as a particularly effective self-management tool. Next, Dr. Christine Paulsen, from the American Institutes of Research (AIR), presented on expert reviews and usability testing. Dr. Garry Welch presented on his experiences using CDMP for bariatric surgery, and his involvement in the Hispanic initiative in Springfield. Lastly, Kevin Nickels, CEO of Celleration presented on their medical product dealing with the use of specialized ultrasound technology as a wound healing mechanism.

JVN Development at Joslin Diabetes Center

There have been 2 major drivers that have dictated the technical development of the JVN Eye Care component of this project as outlined below:

1. The requirement to integrate the JVN system into AHLTA required an acceleration of the integration of the JVN Eye Care application as a module of the CDMP application. The aim here was to provide a single application that encompassed all our development work both in eye care and diabetes care into a single application that was ready for integration into AHLTA. This

critical step has been accomplished together with added functionality into JVN Eye Care with the release of the next generation of JVN software (JVN 4.0)

2. With emerging technology the current JVN eye care analog video cameras were no longer being produced which required a development effort to define the specifications for a digital non-mydratic retinal fundus imaging camera that conformed to the JVN specifications for low light level imaging. The discovery process resulted in a partnership with MegaVision to develop the required retinal imaging camera (RIC)

The functional requirements for the JVN 4.0 software were defined during the course of 48 hours over 6 weeks of facilitated functional requirements specification meetings during Nov and Dec of 2005. These requirements were agreed upon by all participants and the Joslin based software development team (Frank Wang, Kelley Gardner, Marc Van Marter and Harry Chao) working closely with Estenda Solutions initiated software code development based on the identified requirements. The JVN 4.0 application code development is currently complete and undergoing user acceptance testing at Joslin. Upon completion of UAT in November we will initiate a clinical validation study to validate the diagnostic accuracy of the MegaVision digital camera technology. Based on initial evaluation the retinal image quality that meets our JVN specifications is significantly superior to any other video camera capture system currently available.

JVN IMAGER

JVN 4.0 Imager is an image acquisition product for capturing retina images based on the previous product JVN V3.0 (IA). MegaVision's digital camera back has been integrated in JVN V4.0 Imager. We have completed the following new features and enhancements:

- Add MegaVision's RIC Digital Camera to the product
- Allow to save original raw image data
- Re-program the product with Microsoft.NET technology to eliminate the troublesome product architecture generated by an outsourcing company. With the new Microsoft.NET technology, the architecture and product reliability will be dramatically improved.
- Resolve defects reported from previous releases.
- Improve user interfaces and product performance.
- Improve Modality Work List search engine.
- Support the compatibility of existing image acquisition devices

JVN SERVER

JVN 4.0 Server, a subset of the CDMP server, is an image and information management server that provides permanent storage capabilities of ophthalmic image and related information. Its function is mainly to provide "on-demand" distribution of diagnostic images of ophthalmic photography and related clinical reports of diagnosis, and also to automate permanent storage with virtually unlimited storage capacity. It is a service-provider oriented server that will be normally located in Joslin Diabetes Center, or perhaps other centralized hospital/clinic locations, if necessary. Furthermore, it provides features that contribute to the enhanced workflow of ophthalmologists and other ophthalmologic clinicians. It also provides information management features to those administrators who perform daily clinical and technical supports. The JVN Server consists of two major components: JVN DICOM Server and JVN Reader that leverages CDMP data monitoring and reporting capabilities. We have completed following major features:

DICOM Server

DICOM exists as the universal glue to connect JVN Server with JVN Image Acquisition and potentially any external 3rd Party DICOM Systems. This is the interface over which JVN Server will receive images, structure reports, and HIS scheduling events. DICOM is also used to transmit images and structure reports out to other systems, but only when the "On-Demand" interface is not applicable.

The "On-Demand" Interface is a proprietary interface for the transmission of the images and managing of the workflow related to those images. The "On-Demand" Interface allows studies to be locked to a particular user, and the status of the study to be altered accordingly. This interface also offers a faster mechanism for the transmission of images to the requesting viewing workstation.

- Support DICOM XC and OP images

- Support DICOM Structure Report – SR obje22cts
- Support DICOM Storage SCP
- Support DICOM Modality Worklist Provider SCP
- Support DICOM Storage Commitment SCP

2. HIS/HL7

- Support HL/7 message listening and parsing functions

3. Storage

- Support for RAID Level 5 or higher storage configurations
- Support for SAN/NAS configurations for permanent storage as integrated long-term storage
- Support for storing data into Oracle database
- Support for storing images and reports to the file system

4. Image Compression

- Support for standard JPEG2000 color compression and decompression

5. UI (User Interface)

- Web Server with Microsoft ASP.NET technology
- Support Web-based clinical user interfaces (see Reporter features)
- Support Web-based clinical reporting functionality (see Reporter features)
- Support Web-based administrative reporting functionality for clinical services
- Support Web-based administrative functionality for technical services
- Support a proprietary interface to provide “On-Demand” style functionality to JVN Reader.

6. Reporter

- Support a server application integrated with the JVN Reader client application
- Support study worklist display and filtering
- Support the entry of clinical findings and other patient data
- Support algorithms for the determination of potential eye diagnoses and risks
- Support review and distribution of completed JVN study reports

JVN READER

JVN Reader V4.0 is a Microsoft Windows based application that leverages CDMP for its reporting and storage functionality. This application has been designed with a large number of features to meet the needs of ophthalmic photography image display and diagnosis. We have completed following major features:

- Worklist and Clinical Findings interfaces – will access JVN Reporter and provide end users with patient/study worklist, clinical findings templates, and clinical reports templates. By linking to JVN reporter and JVN DICOM server, the interfaces will also provide a mechanism to download patient study related images for further diagnosis.
- Diagnostic Display – Diagnostic image display is a major software component that consists of a set of standard image process tools and a set of advanced image process tools. Diagnostic images are displayed on a thumbnail monitor and primary viewport monitor. Diagnosis can be done through using the thumbnail display and primary display, combined with the image process and manipulation tools.
- Reader-Server collaboration engine - JVN Reader uses the engine to communicate with JVN server where the study images are physically stored. This engine will triangulate JVN

Reporter-Sever-Reader three parties to make web HTTP linking, image downloading and event notifications.

JVN/CDMP Development: Estenda Solutions.

The Comprehensive Diabetes Management Program (CDMP) software solution was significantly enhanced during the 2005-2006 reporting period. CDMP is comprised of five independent software systems that share a common integrated technical architecture. While each of the five components received enhancements over the period, the most significant modifications were made to the Clinical and tele-opthamology applications. In addition to the progress summarized in this section, Estenda Solutions played a critical role in the support of CDMP for the Usability Study described above as well as rapidly implementing some of the critical modifications identified from this study.

Routine maintenance and enhancement

During the reporting period the Estenda team developed two major versions of the software culminating in the now current version 4.5. Over 100 miscellaneous updates were made as the team addressed user feedback issues across the suite.

Ongoing research support

During this reporting period the Estenda technical team supported four live clinical trials conducted at the Boston VA, Joslin Diabetes Center and Walter Reed Army medical center. To accommodate various technology restrictions the team was able to implement CDMP's study management module on several unique platforms including dated laptop technology. The team also assisted principal investigators with access, formatting and analysis of the resulting study data.

Ongoing implementation support

Modules from the CDMP suite are currently installed at a variety of locations both as part and in addition sites collaborating on this grant. During the reporting period the technical team support installations at: Joslin Diabetes Center; the Boston VA; Walter Reed Army Medical Center; 3 Hawaii based community health centers.

Clinical application

The clinical application underwent significant revision when incorporating functional changes resulting from the independent CDMP usability study conducted by the American Institutes of Research (AIR). Changes were made to key areas such as patient and population alert filtering, care planning. Various findings from the AIR study are included below:

Positive Findings

1. Testers were enthusiastic about the layout of the application, the types of data available on the application's clinical pages, and the application's ability to share patient data among team members.
2. Testers were able to successfully complete tasks that required them to locate existing clinical data for a specific patient.
3. Testers found it easy to read and understand the patient-specific clinical pages.
4. Testers wanted and expected the ability to customize the CDMP for their own use. This is a positive finding as the application was designed for such customization. It will be customized at each site that uses it at the time of implementation.
5. Testers did not quickly grasp all concepts (i.e., the Care Plan, Alerts, Reminders and some CDMP-specific rating scales). Given testers received only a brief training, it remains to be determined whether full training in the application would increase speed of understanding.

Findings Suggesting Areas for Improvement

1. Testers' presuppositions about what the application could do were not always congruent with the application's functionality. This suggested concrete ways that we might refine the application and/or develop training materials.
2. Testers thought certain lists (such as "Action Items" for patients and care managers) were in not intuitive order.

3. Testers thought that drop-down menus were not an appropriate tool for items where they wanted to make more than one choice.
4. Testers thought error messages should be easier to read.
5. Testers thought that items unique to the CDMP (e.g., ratings scales) should be explained clearly so that even long-time users of the application may interpret the information correctly.

Tele-ophthalmology application (JVN Eye Care)

During this reporting period significant progress was made to bring the existing tele-ophthalmology application onto the CDMP common platform that required a close collaborative effort between the Joslin technical team involved in expanding JVN eye care functionality and the CDMP Estenda team. This infrastructure consolidation had several benefits including: Improved usability and maintainability, reduced infrastructure cost, and ability to be integrated into major DoD facilities such as Walter Reed Army Medical Center and AHLTA.

The system's capabilities for remote retina analysis, diagnosis and treatment planning were significantly improved by the development of a comprehensive reading center workstation. These new workstations consist of four high resolution monitors that allow the image reader to simultaneously view patient data, record findings, select various images, manipulate images and simulate three-dimensional retinal images. By integrating the reading station on the CDMP platform, clinicians are now able to incorporate the patient's full medical history including systemic risk factors for the progression of Diabetic Retinopathy (such as hypertension and hyperlipidemia) Clinical workflow and Quality Assurance is also greatly improved with the new application that uses CDMP's patient identification and clinical worklist components. The application supports the following clinical workflow. The imaging modality is notified of scheduled patients, this notification prepopulates the modality with all required demographic and medical history data. The imaging technician uses this information during the encounter to provide real time education and identify emergent conditions. After imaging the modality transmits the completed study directly to the CDMP server via the newly developed DICOM interface. By incorporating DICOM communications in the CDMP infrastructure the program saves over \$30,000 in annual licensing fees and eliminates products from a software vendor with a poor support organization. The CDMP DICOM engine stores the study and presents it for evaluation on the reader's desktop. Once presented and selected from the reader's worklist all study related information is streamed to the reading workstation. The study is presented to the reader across four screens, the reader evaluates the image using a series of image review and manipulation tools (magnification, stereo, measurement, color manipulation, etc) the reader fully documents their findings in the system (including new image quality feedback). Once the findings are saved, the CDMP determines various ophthalmologic diagnoses using a set of algorithms (these algorithms were also enhanced during this reporting period to take full advantage of the new capabilities) The diagnoses are then presented to the reader for review, final comment and development of a patient specific treatment plan. After the user signs the study report it may be automatically emailed (via 128 bit encrypted .pdf file), faxed or electronically submitted back to the referring physician.

By moving the tele-ophthalmology application to the CDMP platform the team was also able to incorporate a full Quality Assurance program into the software. During this reporting period the team developed both criteria and workflow for program quality assurance. The system is capable of both enforcing random, blinded peer-to-peer and peer to supervisor quality assurance reviews, reading center to imaging station reviews as well as custom group comparisons. To further improve program quality and reader productivity any reader may automatically request a supervisor or peer consult on a given study at any time during the reading process.

Key Research Accomplishments

- All proposed Prospective Research Studies are either initiated, in recruitment, or completed
- Associated manuscripts for completed studies are in preparation for submission to peer review journals
- Completed integration of JVN eye Care into CDMP with development of next generation software
- JVN application is completed and ready for integration into AHLTA
- Definition of requirements for a retinal digital imaging camera, development of camera and initiation of clinical validation trial to determine diagnostic accuracy
- Expanded CDMP functionality to include a broader range of home monitoring devices in partnership with iMetrikus

- Implementation of data monitoring in CDMP to provide quality assurance reporting on the JVN eye care program
- Establishment of a research data warehouse of JVN eye care patients with a manuscript in preparation, using this data, comparing Joslin patients undergoing JVN eye care intervention compared to Joslin patients receiving standard care with respect to outcomes such as compliance to eye care referrals, glycemic control, lipid levels, blood pressure, and foot examinations

Reportable Outcomes

Invited Presentations

- 2005 American Telemedicine Association Annual Meeting: Denver, CO
Telehealth Practice Recommendations for Diabetic Retinopathy Joslin Vision Network: Category 3 Telemedicine for Diabetic Retinopathy
- 2005 Longwood Medical Ophthalmology Monthly Conference. June 2005.
Joslin Vision Network Diabetes Eye Care Model: Principles and Applications
- 2005 Canadian Ophthalmological Society Annual Meeting. Edmonton, Alberta, Canada *American Telemedicine Association Telehealth Practice Recommendations for Diabetic Retinopathy*
- 2005 International Symposium on Diabetic Retinopathy, Medical Council of India, Aravind Eye Hospital, Madurai, India. 3-4 September 2005
Telemedicine Practice Recommendations for Diabetic Retinopathy
Joslin Vision Network Telemedicine Diabetes Eye Care Model: Principles and Applications
- 2005 Harvard Medical School: Diabetes Mellitus State of the Art: An Integrative Approach to Understanding and Managing Diabetes *The Joslin Vision Network—Validated Telemedicine for Diabetic Retinopathy*
- 2005 Joslin Diabetes Center; Affiliated Center Annual Meeting
Joslin Vision Network Telemedicine Diabetes Eye Care Model: Principles and Applications
- 2005 Koch Eye Associates Grand Rounds, Warwick, RI.
Perspectives: Diabetic Retinopathy and Telemedicine
- 2006 Optometric Retina Society. Retinal manifestations of Vascular and Related Systemic Disease—3rd Annual Meeting, Boston, MA
Diagnosing and Managing Diabetic Retinopathy: Essentials for the Primary Care Optometrist
- 2006 Annual Meeting, San Diego, CA.
Imager and Grader Certification and Quality Assurance in Ocular Telemedicine

Posters/Abstracts

1. Chow SP, Cavallerano J, Katalinic P, Hock K, Tolson A, Kirby A, Aiello LM, Aiello LP, Bursell S. Detection of non-diabetes-related pathology in diabetic patients using nonmydriatic digital retinal imaging compared to dilated clinical eye exam. 2005 American Telemedicine Association Annual Meeting: Denver, CO.
2. Hock K, Cavallerano J, Kirby R, Frey L, Tolson A, Aiello LM. Poster. The effect of an adult-diabetes-clinic-based nonmydriatic retinal imaging program on access to diabetes eye care. American Diabetes Association 2005 Annual Meeting. San Diego, CA
3. Sackey J, Heffernan J, Tolson A, Cavallerano J. Innovations in Managing Diabetic Retinopathy in a Primary Care Practice. Society of General Internal Medicine (SGIM) 29th Annual Meeting. Los Angeles, CA.
4. Ceron OM, Simmons EP, Robles L, Garcia E, Cavallerano J, Timothy N, Calderon R, Caballero AE, Aiello LP. Integration of Ocular Telemedicine and Specialty Diabetes Care in a Latino Population. ARVO 2006 Annual Meeting, Fort Lauderdale, FL.
5. Doughty J, Heffernan J, Sackey J, Chew R, Eagan S, Tolls D, Aiello LP, Tolson A, Cavallerano J. Nonmydriatic Retinal Imaging for Diabetic Patients in a Primary-Care Setting. American Telemedicine Association 2006 Annual Meeting, San Diego, CA.
6. Hock K, Cavallerano J, Kirby R, Frey L, Tolson A, Bursell S-E, Aiello LM. Nonmydriatic Retinal Imaging in an Adult Diabetes Clinic. American Telemedicine Association 2006 Annual Meeting, San Diego, CA.

7. Birkmire-Peters, D.P. (2006). Use of Human Factors Principles in Telemedicine Research. Paper presented in The People Make the Difference: Human Factors in Telemedicine Panel at the 11th Annual Meeting of the American Telemedicine Association, San Diego, CA.
8. Coll, K.J., Birkmire-Peters, D.P., Pelletier, M.V., Cavallerano, J., Bursell, S., Winkle, R.K. & Aiello, L.M. (2005, April). Joslin Vision Network: Eye Care Visits Following JVN Imaging. Poster presented at the 10th Annual Meeting of the American Telemedicine Association, Denver, CO.
9. Bursell SE, Birkmire-Peters D, Conlin P, Fonda S, Kedziora RJ, Paulsen C, Perkins J, Rodbard D, Vigersky R. Human Factors Analysis: Joslin Vision Network Comprehensive Diabetes Management. American Telemedicine Association 2006 Annual Meeting, San Diego, CA.

Publications

1. Wilson C, Horton M, Cavallerano J, Aiello LM. Addition of primary-care based retinal imaging technology to an existing eye care professional referral program increased the rate of surveillance and treatment of diabetic retinopathy. *Diabetes Care* 2005; 28:318-322.
2. Cavallerano AA, Cavallerano JD, Katalinic P, Blake B, Rynne M, Conlin P, Hock K, Tolson AM, Aiello LP. A telemedicine program for diabetic retinopathy in a Veterans Affairs Medical Center—the Joslin Vision Network Eye Health Care Model. *Am J Ophthalmol*. 2005;139:597-604.
3. Cavallerano JD, Aiello LP, Cavallerano AA, Katalinic P, Hock K, Kirby R, Aiello LM, Joslin Vision Network Research Team. Nonmydriatic digital retinal imaging alternative for annual retinal examination in persons with previously documented no or mild diabetic retinopathy. *Am J Ophthalmol* 2005;140:667-673.
4. Whited JD, Datta SK, Aiello LM, Aiello LP, Cavallerano JD, Conlin PR, Horton MB, Vigersky RA, Poropatich RK, Challa P, Darkins AW, Bursell SE. A modeled economic analysis of a digital teleophthalmology system as used by three federal healthcare agencies for detecting proliferative diabetic retinopathy. *Telemedicine and e-Health* 2005;11:641-651.
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6. Cavallerano J, Aiello LM. Emerging trends in ocular telemedicine: the diabetic retinopathy model. *Journal of Telemedicine and Telecare*. 2005; 11:163-166.

Conclusions

The study design for the proposed multicenter prospective clinical trials have been completed, have received approval through participating organization human subjects review boards, and have been approved through HSRRB. The proposed studies are in various stages of initiation, recruitment, or completion. For completed studies data has been analyzed and manuscripts are being prepared for submission. These prospective studies are important as they are designed to demonstrate both clinical efficacy and cost effectiveness of the JVN program. If the hypothesis of clinical efficacy and cost effectiveness are born out by the results from these trials then the broad introduction of this application into the health care system will be facilitated and could result in significant health care dollar savings associated with the care of patients with diabetes.

The Comprehensive Diabetes Management Program (CDMP) application has undergone a number of versions and we have developed significant new functionality to the application. The CDMP architecture was key in the seamless integration of the JVN eye care program as a module of the CDMP application. The integration of JVN eye care into CDMP was a critical step to complete integration of a single application into AHLTA.

The JVN Eye care module has also undergone significant revision that incorporates increased reporting functionality for both diabetic retinopathy and other non-diabetes related eye diseases such as age related macula degeneration. The reporting functionality also leverages CDMP risk assessment so that a clinical plan for appropriate eye care also takes into account systemic risk factors that may increase the progression of diabetic retinopathy. Additionally, because analog video cameras, are no longer available we have had to research digital video cameras that can be used to meet the requirements for low light level retinal imaging without pupil dilation. This research has been completed in partnership with MegaVision where we have developed a digital camera with superior imaging capabilities that continues to meet JVN requirements for low light level imaging. This camera is currently undergoing rigorous clinical validation for diagnostic accuracy.

With the completion of the CDMP patient portal (Diabetes Management Everywhere (DME) and its utilization in a prospective clinical trial we have worked on expanding DME functionality to support a broader range of home monitoring devices. In order to accomplish this we have established a partnership with iMetrikus who have developed a universal adaptor that allows communication between multiple devices through DME to the CDMP server. The DME portal facilitates secure communication between patient and provider with respect to downloaded patient information such as weight, blood pressure, and blood glucose monitoring values. The system also allows patients to download digital images for review by care managers, for example patients can download images of their meals for discussion regarding portion size and calories with nutritionists.

Appendices

Appendix #1: Web-Based Care Management in Patients With Poorly Controlled Diabetes. GRAHAM T. MCMAHON, HELEN E. GOMES, SARA HICKSON HOHNE, TANG MING-JYE HU, BETTY A. LEVINE, PAUL R. CONLIN (Attached as a pdf below)



APPENDIX #2: THE RELATIONSHIP OF INTERNET-BASED CARE MANAGEMENT AND CHANGES IN GLYCEMIC CONTROL TO DEPRESSIVE SYMPTOMS AND DIABETES-RELATED DISTRESS. STEPHANIE J. FONDA, GRAHAM T. MCMAHON, HELEN E. GOMES, SARA HICKSON, PAUL R. CONLIN. SUBMITTED FOR PUBLICATION (ATTACHED AS A PDF BELOW)



Appendix #3: Abstract Submitted to CDC Conference

Test-Retest Reliability of a New Screening Questionnaire for People with Diabetes

Jeonifer Garren, MPH, Stephanie J. Fonda, Ph.D, Sven-Erik Bursell, Ph.D., Paul R. Conlin, M.D., Robert A. Vigersky, M.D., Deborah Birkmire-Peters, Ph.D.

OBJECTIVE: To analyze the test-retest reliability of a new 39-item questionnaire for people with diabetes, called the Behavioral Assessment Tool (BAT). The questionnaire was designed to help clinicians and care managers quickly identify areas for improvement in patients' self-care regimens and patients' barriers to self-care. **METHODS:** We recruited 43 subjects from Joslin Diabetes Center (Boston). Each subject completed the BAT twice, 2-4 weeks apart. Basic health and social-demographic data were also collected. The correlations between the responses to BAT questions were examined. **RESULTS:** The sample was 70% female and 84% white. Seventy percent of the sample had type 2 diabetes. The average age of the subjects was 61 ± 13 years. Eighty-eight percent of the subjects completed the study; dropouts were not significantly different demographically from completed subjects. Overall reliability ranged from 0.47 - 1.0. Reliability coefficients ranged from 0.53 - 1.0 for questions about nutrition, physical activity, blood glucose monitoring, alcohol use, mood, and social support. **CONCLUSIONS:** Test-retest reliability for the BAT is high and comparable to other instruments. This first evaluation of test-retest reliability suggests that the BAT may be appropriate for clinicians and care managers to identify problems in patients' self-care regimens and refer them for further evaluation. **LEARNING OBJECTIVES:** Create efficient and effective methods to measure current behavior of people with diabetes. **KEY WORDS:** Diabetes, reliability, behavior

Appendix #4: Human Factors Analysis: Joslin Vision Network Comprehensive Diabetes Management Program. Bursell, Birkmire-Peters, Conlin, Fonda, Kedziora, Paulsen, Perkins, Rodbard, Vigersky.



**The Relationship of Internet-based Care Management and Changes in Glycemic Control
to Depressive Symptoms and Diabetes-Related Distress**

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Running Head: Internet-based care management

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Abstract**Purpose**

To examine the effects of an Internet-based care management program -- tailored to address metabolic control -- on depressive symptoms and diabetes-related distress in patients with diabetes. We additionally examined the relationship of improvement in glycemic control with depressive symptoms and diabetes-related distress.

Methods

Patients with A1c levels of $\geq 9.0\%$ were randomized to usual care or an Internet-based care management program. Depressive symptoms were measured using the Center for Epidemiologic Studies – Depression Scale. Diabetes-related distress was measured using the Problem Areas in Diabetes Questionnaire. We assessed participants at baseline and every 3 months for 12 months. Improvement in glycemic control was defined as a reduction of ≥ 1 percentage points in A1c (i.e., a clinical response in A1c). Linear mixed models were used to analyze the data.

Results

Depressive symptoms did not vary over time whereas diabetes-related distress declined significantly. These patterns were not related to treatment group. Clinical response in A1c did not relate to the rate of change in depressive symptoms; however, participants who had a clinical response in A1c had the greatest drop in diabetes-related distress scores vs. other participants. Participants in the care management group who had a clinical response in A1c experienced the greatest improvements in diabetes-related distress.

Conclusions

Improved glycemic control, how ever achieved, may contribute to reductions in diabetes-related distress. Internet-based care management program may further enhance the benefits for diabetes-related distress gained from improvements in glycemic control.

Adherence to a healthy diet, regular exercise, judicious use of diabetes medications, regular blood glucose monitoring, smoking cessation, and regular clinic visits can reduce the morbidity and mortality associated with diabetes.^{1,2} However, combining these lifestyle/behavioral strategies can be as hard to learn and complicated as flying a “modern supersonic aircraft.”³

Lifestyle/behavioral strategies and change are facilitated by education or self-management training⁴ and care management,⁵ but diabetes frequently coexists with problems of affective functioning that may impede the benefits of these things. For example, depression and depressive symptoms are significantly more common for people with diabetes than they are for people without diabetes.⁶⁻¹⁰ Additionally, people with diabetes frequently experience disease-related stress, such as fears about the disease getting worse, fears of hypoglycemia, and feelings of failure with respect to self-care efforts.¹¹ Problems with affective functioning are reciprocally related to people’s ability to initiate or sustain appropriate behaviors for managing their disease.¹²⁻¹⁵ In turn, problems with affective functioning are associated with poorer metabolic control overall¹⁶, especially if the lifestyle/behavior regimen required to bring it under control is intense (such as a regimen that necessitates multiple insulin injections per day).¹⁷

Care management interventions designed specifically to treat poor affective functioning among people with diabetes have had mixed results. Katon and colleagues,¹⁸ for example, found that an intensive care management intervention for people with both diabetes and depression reduced ambulatory medical costs, whereas Lin and colleagues¹⁹ found that a different care management intervention for people with both diabetes and depression had no effect on diabetes-related self-care. Care management interventions designed specifically to improve patients’ glycemic and blood pressure control seem to have more consistently positive results.²⁰⁻²² These latter care management interventions were not designed for people with comorbid problems of affective functioning per se, but Trief and colleagues²³ have shown that

their care management intervention targeting glycemic control was as effective for people with diabetes and comorbid depression as it was for those without depression.

We sought to determine whether an Internet-based care management program focused on improving metabolic control was related to change in affective functioning, namely depressive symptoms and diabetes-related distress. McMahon and colleagues²¹ have documented substantial drops in HbA_{1c} (A1c), blood pressure, and lipids for participants of this program. Do the favorable effects of the program extend beyond the initial targeted outcomes (i.e., A1c, blood pressure, and lipids) and relate to more distal outcomes that previous research shows can impinge on whether people sustain behavioral change (i.e., affective functioning)? Further, do improvements in glycemic control relate to change in affective functioning? To address this latter question, we also examined whether change in depressive symptoms and diabetes-related distress was related to changes in glycemic control as assessed by clinical response in A1c.

Methods

Subjects

One hundred and four subjects with poorly controlled diabetes (A1c level ≥ 9.0 percent) at the time of screening were enrolled from the Department of Veterans Affairs (VA) Boston Healthcare System, as previously described.²¹

All participants attended a half-day self-management education session for instruction in diabetes core-content areas as recommended by the American Diabetes Association.²⁴ We then randomized participants to usual care with their primary care provider as needed (n=52) or Internet-based care management (n=52). Participants in the care management group received a notebook computer, a glucose meter, a blood pressure monitor, training in the use of all study devices, complimentary toll-free dial-up Internet service, and access to the secure diabetes education and management website used throughout the study (MyCare Team;

<https://mycareteam.georgetown.edu/vaboston>). The website a) accepted electronic transmissions from blood pressure and glucose monitoring devices and displayed these data in graphic and tabular form for the participant and care manager to review, b) allowed participants to send and receive secure messages to and from the care manager, and c) contained web-enabled diabetes educational modules and links to other web-based diabetes resources. Participants in the care management group were encouraged to perform home blood pressure monitoring at least three times weekly; recommendations for home glucose testing were individualized for each patient. An advanced practice nurse certified as a diabetes educator reviewed participant data from the website and, using treatment algorithms for glucose and hypertension management, provided care recommendations to the primary care provider and participants. The care manager and participants maintained contact through the website's internal messaging system and occasionally through telephone contact.

We collected outcomes data from all participants at baseline, 3, 6, 9, and 12 months after enrollment. After randomization, participants in the usual care group had no contact with study staff other than the data collection visits.

Measures

Depressive symptoms were measured using the original, twenty-item Center for Epidemiologic Studies-Depression (CES-D) scale. The CES-D scale measures a continuum of current symptoms of depression and anxiety, rather than the presence of known psychiatric disorders.^{25,26} For these analyses, we used a single summary measure of participants' answers to the CES-D questions. We coded all items to indicate the frequency of symptoms participants might have experienced within the last week (0 = none of the time to 4 = most or all of the time). Positively worded items were recoded to be consistent with the other items in the scale. The sum of the items could range from 0 to 60, with higher scores indicating worse affective functioning.

For the assessment of diabetes-specific emotional distress, we used the Problem Areas in Diabetes (PAID) scale. The PAID scale comprises 20 items summed to provide a total score of emotional distress. It has high internal reliability (> 0.90), sound concurrent validity as determined by moderate to strong correlations with a range of theoretically-related measures, and responsiveness to change during brief psychosocial and educational interventions.^{27,28} Welch and colleagues²⁹ showed effect sizes between 0.30 and 0.65 for the PAID scale across different psychosocial, educational, and medical interventions for diabetes. Each item is coded to indicate the severity of a problem (0 = not a problem to 4 = serious problem). We summed the 20 items and multiplied by 1.25 to yield a final score between 0 and 100.

To measure changes in glycemic control, we created a series of difference scores for each time point. These scores were then dichotomized such that differences of ≥ 1 A1c percentage points were set to “1” and all others set to “0”. We used one percentage point as the cut-off because the United Kingdom Prevention of Diabetes Study has shown that a drop of about 1% in A1c is clinically significant, leading to about a 50% drop in the rate of diabetes-related complications.³⁰ Thus, these variables represent whether participants experienced a “clinical response in A1c” at each time point. Twenty-seven percent of participants ($n = 27$) did not have a clinical response in A1c over the 12 months of the study. The remainder experienced a clinical response in A1c as of one or more study assessments: the greatest fraction [43.2% ($n = 45$)] of participants had a clinical response in the initial 3-month observation period without further significant improvement; 10.6% ($n = 11$) had a response as of the 6-month observation but not at later observations; 4.9% ($n = 5$) had a response toward the end of the study; and another 13.7% ($n = 14$) had more than one clinical response in A1c.

We carried forward the last observation for measures with missing data. This approach balanced the data within subjects.

Data Analysis

The focal predictors of the data analyses were time, participants' group status (or treatment group) at baseline, and time-varying clinical response in A1c. Assignment to the usual care or the Internet-based, diabetes care management group was random and we used treatment assignment at time of enrollment ("intention-to-treat") in all analyses.

The analyses proceeded in several steps. First, we examined the baseline characteristics of the study participants overall and by treatment group and tested for group differences using t-tests and chi-square tests. Second, we estimated a series of linear mixed models for longitudinal data. Models 1a and 1b were baseline models for change over time and characterized participants' 12-month patterns in depressive symptom and diabetes-related distress scores, respectively. These models only included a variable for time, measured as 0 (baseline), 1 (3 months), 2 (6 months), 3 (9 months), and 4 (12 months). Models 2a and 2b estimated the rate of change over time in depressive symptom and diabetes-related distress scores due to treatment group assignment and the interaction of treatment group assignment with time. Models 3a and 3b estimated whether the rate of change over time in depressive symptom and diabetes-related distress scores differed by clinical response in A1c and the interaction of clinical response in A1c with time. Lastly, we added a number of social-demographic and health characteristics (age, race/ethnicity, education, duration of diabetes, etc.) to the linear mixed models, but our conclusions regarding the effects of the focal variables did not change. Consequently, we report result from the parsimonious models.

All mixed models specified the autoregressive covariance structure with heterogeneous variances for the within-subject variance covariance matrix. All calculations were performed using SAS version 9.1 software (SAS Institute, Cary, North Carolina, United States).

Results

At baseline, the mean age of the participants was 61 years and the sample was predominantly male (99%), non-Hispanic white (77%), currently married (61%), and had attended some college or more (67.3%) (see Table 1). The average duration of diabetes was 12.5 years, about 49% were taking oral medications (only), and 51% were taking insulin. The participants' average A1c level at baseline was 9.9%. The average, unadjusted CES-D score at baseline was 12.2. Twenty-seven percent of the study participants had CES-D scores of 16 or more at baseline. The average, unadjusted PAID score was 25.1. The treatment groups were not statistically different with respect to these unadjusted baseline social-demographics, health characteristics, and domains of affective functioning.

[Table 1 about here.]

Change over Time

Table 2 reports the patterns in depressive symptoms and diabetes-related distress scores over time, before and after considering the effects of treatment group assignment and clinical response in A1c. Diabetes-related distress declined significantly and progressively from baseline; the average drop in PAID score was 1.80 per every 3 months ($p < 0.001$) (see Model 1b). This rate of change meant that the average baseline PAID score of 23.22 was reduced to 16.02 by 12 months, a reduction of 31%. The mean CES-D score did not change significantly over time, dropping by 0.23 per every three months from an average baseline score of 12.21 to 11.29 at 12 months ($p = 0.136$) (see Model 1a).

[Table 2 about here.]

Change by Treatment Group

The rates of change in depressive symptom and diabetes-related distress scores did not differ by treatment group. Specifically, the CES-D and PAID scores of participants in the treatment group changed at a rate of 0.12 ($p = 0.702$) and 0.59 ($p = 0.222$) per every 3 months, respectively (Models 2a and 2b in Table 2).

Change by A1c

Clinical response in A1c was related to diabetes-related distress as measured by the PAID score (Model 3b in Table 2); the estimated baseline PAID score was 6.23 ($p < 0.001$) lower for participants who had a clinical response in A1c than for those who did not. Moreover, the PAID scores of participants who had a clinical response in A1c declined at a rate of 2.28 per every 3 months ($p < 0.01$). Clinical response in A1c did not relate to baseline CES-D score (-0.01 ; $p = 0.989$) or to rate of change in CES-D score (-0.22 ; $p = 0.635$) (Model 3a in Table 2).

Figure 1 presents fitted trajectories of PAID scores for four prototypical groups using the results from Model 3b. Participants who consistently had a clinical response in A1c had lower PAID scores initially as well as a 54% steeper rate of decline than those who never had a clinical response in A1c. Those who experienced a clinical response in A1c at some point later in the study dropped from the upper trajectories to the lower trajectories. Although treatment group was not significant in the models, the figure suggests that participation in the Internet-based care management group had a modest, positive effect. That is, the care management group's PAID score trajectories were slightly lower than those for the usual care group, irrespective of clinical response in A1c. Participants who both had a clinical response in A1c and were in the care management group had the lowest PAID score trajectories.

[Figure 1 about here.]

Discussion

This study examined the effect of an Internet-based care management program on depressive symptoms and diabetes-related distress in an open, randomized, 12-month trial. The care management program focused on metabolic control, rather than mood per se. All participants had poor glucose control when they enrolled in the study. This study also explored the relationship of change in glycemic control to change in depressive symptoms and diabetes-related distress. Change in glycemic control was defined as a reduction of ≥ 1 percentage points in A1c, which we called a “clinical response in A1c”.

The analyses showed that, among all participants, depressive symptoms did not change markedly over the study and diabetes-related distress declined significantly. Treatment group assignment was not associated with the rate of change in depressive symptoms or diabetes-related distress. Also, clinical response in A1c did not significantly affect study participants' depressive symptoms, but it was a significant factor in participants' baseline and diminution of diabetes-related distress over time. One interpretation of this latter finding is that participants who had lower diabetes-related distress initially were more likely to improve their glycemic control, and as they improved their glycemic control, their diabetes-related distress scores dropped more sharply. Lastly, although treatment group assignment was not significant, examination of prototypes showed that the distress trajectories of the care management group were consistently lower than those for the usual care group. Thus in the context of improvements in glycemic control, there may be an added benefit to participating in an Internet-based care management program.

Theoretical perspectives and previous research point to various and sometimes inconsistent outcomes for Internet-based disease management (including, but not exclusively diabetes care management). One perspective is that the Internet holds promise for disease management because of its ability to facilitate patient's access to their providers, their health

information, and other people with the same or similar chronic conditions. The Internet can also improve provider's access to their patients by enabling patients to upload and send up-to-date personal data (such as blood glucose readings). This facilitated access could lead to positive changes in patient behavior and feelings of social support, to provider efficiency, and ultimately to improvements in patient outcomes. Indeed, several studies have reported a positive association between Internet-based care management for improving metabolic control among people with diabetes.^{20,21} Other studies of Internet-based programs that provided people with access to "personal coaches" and peers (rather than to care managers) have documented psychosocial benefits for participants, particularly increases in participants' perceived social support.^{31, 32} Several studies have found that the psychosocial benefits of their Internet-based programs extended to participants of their usual care groups as well, such that there was a favorable response for all study groups.^{33,34} This latter finding does not necessarily mean that the Internet-based approaches did not work; however it is not possible to discern what their true effects were or whether something else contributed to participants' changes.

Another perspective is that the facilitated access made possible with Internet-based disease management could be burdensome for people with diabetes. The Internet-based program we implemented was concerned with moving poorly controlled diabetics toward recommended standards of control. For some participants in the intervention group, this meant they were coached to greatly increase the frequency with which they tested their blood glucose, were prescribed insulin, were instructed to check their blood pressure daily, and/or were coached to monitor their diets more closely, among other things. In this scenario, affective functioning might worsen with exposure to the new lifestyle/behavioral demands of the Internet-based diabetes management program. Previous research has shown that the intensity of diabetes self-care and treatment is linked to poor affective functioning.¹⁷

Together these competing perspectives provide an explanation for the varied relationships we observed between treatment and the two domains of affective functioning.

Participants of the Internet-based care management program usually experienced increases in the intensity of their diabetes care regimens, yet they did not exhibit a worsening of depressive symptoms or diabetes-related distress compared with participants who received usual care. Indeed, they had lower depressive burden consistently through the study. In this way, the care management intervention was 'neutral' with respect to both group's depressive symptoms and both groups exhibited reductions in diabetes-related distress. This may be because the Internet-based diabetes care management program facilitated access of patients to their providers (and improved social support from the provider), offsetting the burden of more demanding self-care. The extent and specific role of enhanced patient-provider access in patients' physical and mental health outcomes and possible changes in perceived social support are areas for further research.

The positive relationship we observed between clinical response in A1c and lower diabetes-related distress is consistent with much previous cross-sectional^{27, 35-37} and prospective³⁸ research on the association between psychosocial functioning and glycemic control. For example, Mazze and colleagues³⁸ found that improved glycemic control predicted improvement in depression and anxiety. Our finding that clinical response in A1c was not related to depressive symptoms is not consistent with this literature, however. This may be because depressive symptom burden was high for this sample (i.e., 27% had CES-D scores of 16+, widely considered to be an indication of clinical depression) and required targeted intervention. Further research might address whether an Internet-based care management program designed to address both metabolic control and psychosocial care can favorably influence diabetes-related distress as well as other domains of affective functioning.

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Table 1. Means/Percentages for Study Participants' Baseline Characteristics, Overall and by Treatment Group

Variable	Total	Internet-based Care Management	Usual Care	<i>P</i> value
	n = 104	n = 52	n = 52	
Age (years; mean)	60.9 ± 10.3	61.7 ± 10.1	60.0 ± 10.5	0.42
Gender (%)				
Male	99.0	100.0	98.1	0.32
Female	1.0	0.0	1.9	
Race/Ethnicity (%)				
Hispanic	5.8	3.9	7.7	0.59
Non-Hispanic White	76.7	74.5	78.9	
Non-Hispanic Black	13.6	17.7	9.6	
Other	3.9	3.9	3.9	
Marital Status (%)				
Single	11.1	8.2	14.0	0.83
Married/partnered	60.6	63.3	58.0	
Separated/Divorced	22.2	22.5	22.0	
Widowed	6.1	6.1	6.0	
Educational Attainment (%)				
< High School Grad	12.5	17.3	7.7	0.29
High School Grad	20.2	21.2	19.2	
Some College or Above	67.3	61.5	73.1	
Years Since Diagnosis of Diabetes (mean)	12.5 ± 7.8	12.5 ± 7.6	12.5 ± 8.1	0.99

Diabetes Medication (%)

None Reported	1.0	0.0	1.9	0.61
Oral Medication Only	48.5	49.0	48.1	
Insulin	50.5	51.0	50.0	
A1c (mean)	9.9 \pm 0.9	10.0 \pm 0.9	9.9 \pm 0.8	0.25
Depressive Symptoms (mean CES-D)	12.2 \pm 8.9	10.9 \pm 8.8	13.5 \pm 7.5	0.14
Diabetes-related Distress (mean PAID)	25.1 \pm 18.9	23.5 \pm 17.9	26.8 \pm 19.8	0.38

Notes: For the tests for group differences, we used t-test for continuous variables and chi-square tests for the categorical variables.

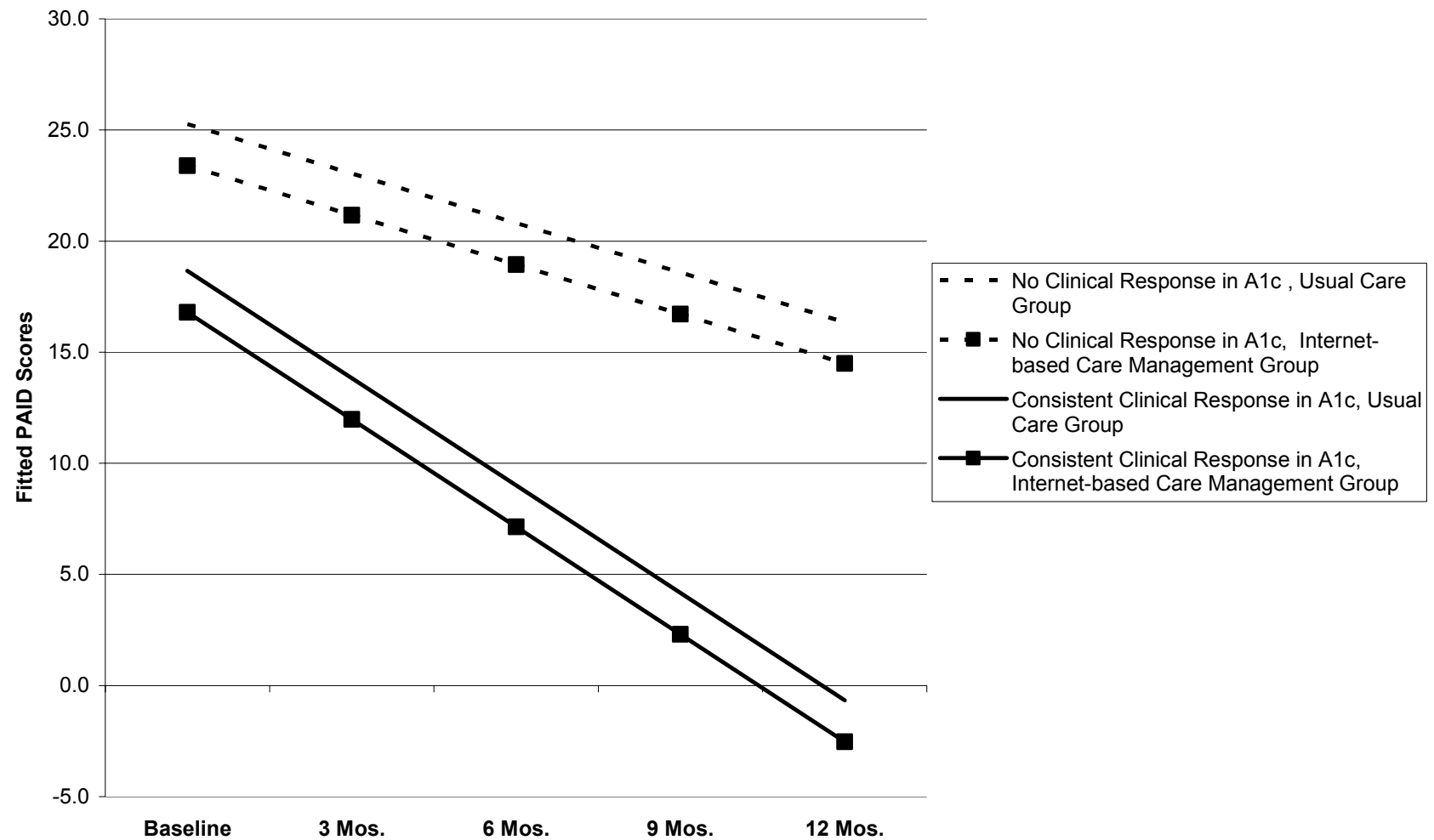
Table 2. Estimated Patterns Over Time of Depressive Symptoms (CES-D Scores) and Diabetes-Related Distress (PAID Scores); Results From Different Linear Mixed Models (n = 104)

[illegible]

Within Person	16.59	***	16.51	***	16.48	***	56.25	***	55.78	***	54.13	***
In Initial Status (Between-Persons)	54.65	***	52.22	***	52.07	***	218.56	***	217.33	***	212.04	***
In Rate of Change (Between-Persons)	1.12	***	1.15	***	1.15	**	1.81	***	1.88	***	1.98	***

Notes: * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$. Standard errors are in parentheses.

Figure 1. Fitted Prototypical Trajectories of Diabetes-Related Distress (PAID Scores)



Web-Based Care Management in Patients With Poorly Controlled Diabetes

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OBJECTIVE — To assess the effects of web-based care management on glucose and blood pressure control over 12 months in patients with poorly controlled diabetes.

RESEARCH DESIGN AND METHODS — For this study, 104 patients with diabetes and HbA_{1c} (A1C) $\geq 9.0\%$ who received their care at a Department of Veterans Affairs medical center were recruited. All participants completed a diabetes education class and were randomized to continue with their usual care ($n = 52$) or receive web-based care management ($n = 52$). The web-based group received a notebook computer, glucose and blood pressure monitoring devices, and access to a care management website. The website provided educational modules, accepted uploads from monitoring devices, and had an internal messaging system for patients to communicate with the care manager.

RESULTS — Participants receiving web-based care management had lower A1C over 12 months ($P < 0.05$) when compared with education and usual care. Persistent website users had greater improvement in A1C when compared with intermittent users (-1.9 vs. -1.2% ; $P = 0.051$) or education and usual care (-1.4% ; $P < 0.05$). A larger number of website data uploads was associated with a larger decline in A1C (highest tertile -2.1% , lowest tertile -1.0% ; $P < 0.02$). Hypertensive participants in the web-based group had a greater reduction in systolic blood pressure ($P < 0.01$). HDL cholesterol rose and triglycerides fell in the web-based group ($P < 0.05$).

CONCLUSIONS — Web-based care management may be a useful adjunct in the care of patients with poorly controlled diabetes.

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Diabetes care is facilitated by a patient's being engaged in a self-management program with the advice and counsel of physicians and allied health professionals (1). Care management has been advocated in diabetic patients as a means of facilitating easier, time-efficient communication between clinicians and patients, with the goal of

improving care and reducing healthcare expenditures.

Healthcare systems have adopted care management for individuals with high-risk diseases, particularly patients with diabetes (2–5). Scheduling and/or travel may be barriers to a patient's engaging with a care provider, thereby limiting uptake and resulting in a failure to maximize

potential health gains (6). Care management has been studied in diabetic patients, but the results have been mixed; some have noted significant improvement in HbA_{1c} (A1C) (7–9), but a recent study found no effect (10).

Patients are accessing medical content on the Internet with increasing frequency (11–14). In a survey of patients in a primary care practice, 54% reported using the Internet for medical information and 60% felt that the information was the same or better than what they received from their doctor (11). Few studies have examined the effects of web-based interventions that provide an interactive component; that is, websites that deliver content as well as feedback to participants (15–17). Our goal was to test the hypothesis that diabetes care management using a web-based system in individuals with poorly controlled diabetes would result in significant and sustained improvement in A1C and blood pressure.

RESEARCH DESIGN AND METHODS

The study was conducted at the Department of Veterans Affairs (VA) Boston Healthcare System. The protocol was reviewed and approved by the institutional review board, and informed, written consent was obtained from each participant. Eligibility criteria included A1C $\geq 9.0\%$, age > 18 years, an ability to understand written and spoken English, and a willingness to use a notebook computer and glucose- and blood pressure-monitoring devices. Participants were required to have a VA-based primary care provider at one of four hospital-based clinics or 10 community-based outpatient clinics and access to a telephone.

Hospital laboratory data were screened monthly for individuals with an A1C $\geq 8.8\%$. Potential participants were sent a letter and/or brochure describing the study, and a follow-up telephone call was attempted at least 2 weeks later to solicit participation. In-person screening was provided to interested and potentially eligible subjects between October 2001 and April 2003 (Fig. 1). Reasons for non-participation, as provided by 353 of the

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Abbreviations: VA, Department of Veterans Affairs.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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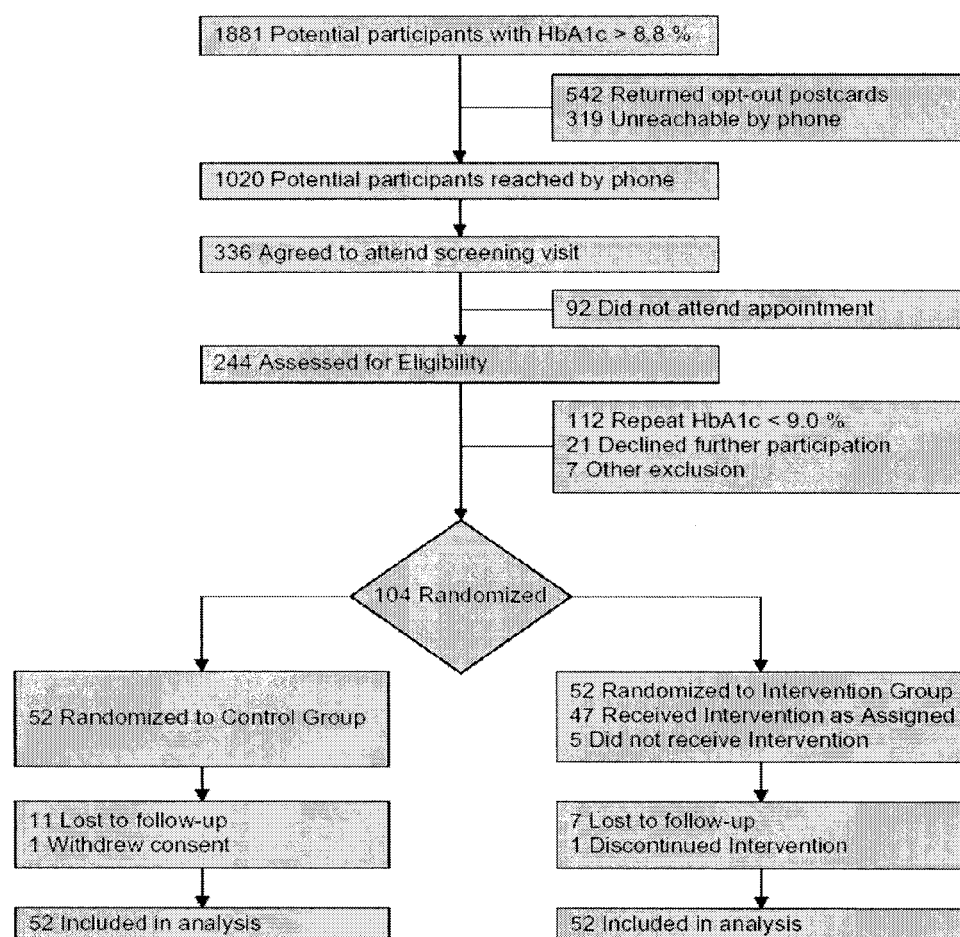


Figure 1—CONSORT diagram of participant flow through the study.

684 individuals who declined to participate after being reached by phone, included a lack of interest (30%), transportation challenges (25%), poor health (20%), scheduling difficulties (9%), and other (16%).

Eligible participants attended a half-day self-management education session for instruction in diabetes core-content areas as recommended by the American Diabetes Association (18). They met with a nurse, nutritionist, and pharmacist, all of whom were certified diabetes educators. Participants were then randomized to one of two study groups through the use of a random variables generator and a series of sealed envelopes.

Participants randomized to usual care continued with ongoing care by their primary care provider as needed. Study staff had contact with these participants only to arrange follow-up visits for outcome measures.

Participants randomized to web-based care management also continued with their usual care but in addition re-

ceived a notebook computer (HP Omnibook, 700 mHz, 128 RAM, running Internet Explorer 5.50), a glucose meter (Accucheck Advantage, Roche Diagnostics), and a blood pressure monitor (HEM-747-IC IntelliSense Automatic BPM; Omron Medical, North Bend, WA). The notebook computer was programmed to connect to a diabetes education and management website (see below) using complimentary toll-free dial-up Internet access. Computer training and support was provided by one of the study staff (S.H.H.) for a mean total of 2.3 h (range 1.0–6.6 h) per subject. Subjects were encouraged to perform home blood pressure monitoring at least three times weekly; recommendations for home glucose testing were individualized for each patient.

The MyCareTeam website (<https://mycareteam.georgetown.edu/vaboston>) was designed and hosted at the Imaging Science and Information Systems Center at Georgetown University Medical Center (Washington, D.C.). Participants used coded identifiers when interacting with

the website, which was accessed using secure socket layer encryption via a secure protocol to ensure the confidentiality of data transfer. The website accepted uploads from blood pressure and glucose monitoring devices and displayed these data in graphic and tabular form for the participant and care manager to review. An internal messaging system allowed participants to send and receive secure messages to and from the care manager via the website. The care manager responded to queries within 1 working day during office hours. The website contained web-enabled diabetes educational modules and had links to other web-based diabetes resources. Participants who did not log into the website during any 2-week period were contacted by a study coordinator by telephone to encourage website usage.

An advanced practice nurse and certified diabetes educator (H.E.G.) reviewed participant data from the website and, using treatment algorithms for glucose and hypertension management, pro-

Table 1—Baseline characteristics of study subjects

	Web-based care management	Education and usual care
<i>n</i>	52	52
Age (years)	64 ± 7	63 ± 7
Sex (% male)	99	100
BMI (kg/m ²)	32.3 ± 5.6	34.1 ± 7.0
Education (%)		
College or above	59	67
High school graduate	22	19
Some high school	12	6
Below high school	6	2
Prior Internet access (%)	31	27
Duration of diabetes (years)	12.4	12.2
Diabetes medication		
Oral medication only	27 (52)	26 (50)
Insulin	25 (48)	26 (50)
Mean A1C (%)	10.0 ± 0.8	9.9 ± 0.8
Blood pressure (mmHg)		
Systolic	141 ± 21	139 ± 20
Diastolic	81 ± 7	80 ± 7
Lipids (mg/dl)		
LDL cholesterol	100 ± 35	97 ± 21
HDL cholesterol	43 ± 14	40 ± 8
Triglycerides	178 ± 112	204 ± 140

Data are means ± SD or *n* (%), unless otherwise noted.

vided recommendations to the primary care provider and participants. The care manager and primary care providers communicated predominantly via the hospital e-mail system; the physician entered medication changes suggested by the care manager directly into the pharmacy's electronic ordering system. The care manager and participants maintained contact through the website's internal messaging system and occasionally through telephone contact.

Outcome measures

The primary outcome measures were A1C and systolic and diastolic blood pressure. Measurements were collected at baseline and 3, 6, 9, and 12 months after randomization. For measurement of A1C, the hemoglobin components were separated using high-performance liquid chromatography, and the six fractions of hemoglobin, including the A1C component, were measured (Tosoh Bioscience, South San Francisco, CA). Blood pressure was measured in the seated position after a 5-min rest with the same automatic blood pressure device used by study participants at home. Two readings were taken 1 min apart and the average of the readings was recorded. Hypertension was

defined as systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg, measured at baseline. Secondary outcome measures (fasting triglycerides and LDL and HDL cholesterol) were obtained at baseline and 12 months and were measured with standard laboratory techniques. Research staff recording outcome measures were not masked to study group assignment.

The protocol prespecified an evaluation of outcomes in the web-based group based on the frequency and persistence of website interactions. During the study, website log-ins and data uploads were counted and time stamped. The number of data uploads over the 12 months of follow-up was separated into tertiles representing medians of 1, 18, and 31 uploads. Persistence with the web-based care management over time was assessed by defining individuals as a "persistent user" (i.e., those who had at least one website log-in every 3 months; *n* = 30) or an "intermittent user" (i.e., those who had intervals >3 months during the study when no website log-ins were recorded; *n* = 22).

Statistical analyses

A sample size of 50 participants in each group was determined to have 80%

power ($\alpha = 0.05$) to detect a between-group difference of 0.8% for A1C, 6 mmHg for systolic blood pressure, and 5 mmHg for diastolic blood pressure. Categorical data are presented as percent and continuous data are presented as means ± SD, unless otherwise noted. All analyses compared subjects according to their status at randomization and were conducted in an intention-to-treat manner, with the last value carried forward for missing data. Baseline characteristics were compared using the χ^2 analysis for categorical variables and the independent groups' *t* test for continuous variables.

Differences between baseline and follow-up for continuous variables were assessed using a mixed linear model incorporating the grouping variable (i.e., randomization or persistence group) as a fixed effect and repeated measures analysis to specify covariance structures for repeated measurements on subjects over time. All tests were two-tailed. For all analyses, $\alpha = 0.05$ was used to define statistical significance. Statistical analysis was performed using SAS 8.02 (SAS Institute, Cary, NC).

RESULTS

Baseline characteristics of the 104 randomized participants, divided by study group, are presented in Table 1. The mean age was 63 years; nearly all were men. The data showed that >50% of the study participants had attended college and ~29% had Internet access before the study.

Changes in A1C

There was a significant decrease in A1C compared with baseline in both groups ($P < 0.001$) at all serial points of measurement (Fig. 2). There was a greater decline in A1C over time in the web-based group when compared with the usual care group ($P < 0.05$). At 12 months, the reduction from baseline in A1C was $-1.2 \pm 1.4\%$ in the usual care group versus $-1.6 \pm 1.4\%$ in the web-based group.

Individuals who had greater adherence with the intervention had more improvement in A1C. Participants in the web-based group who had more data uploads or regular website interactions had greater improvements in A1C. Persistent users tended to have a greater change in A1C when compared with intermittent users (-1.9 ± 1.2 vs. $-1.2 \pm 1.4\%$; $P = 0.051$) or the usual care group ($P < 0.05$) that persisted over time (Fig. 3A). Simi-

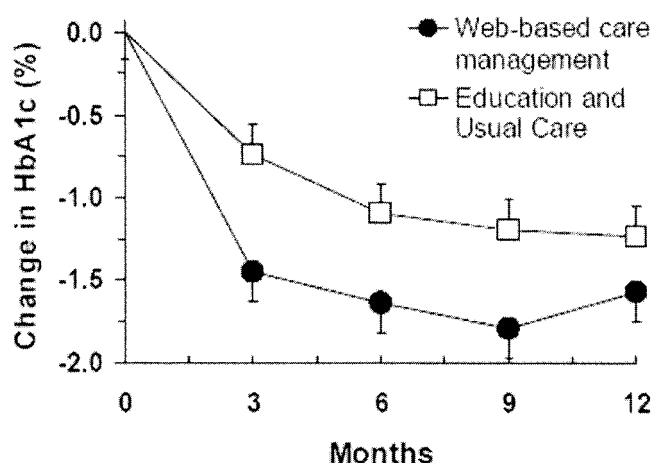


Figure 2—Changes in A1C over 12 months in the usual care and web-based groups. Participants in the web-based group had a significantly greater change in A1C over time ($P < 0.05$) when compared with the usual care group. Data are means \pm SE.

larly, there was a progressive decline in A1C with an increasing number of website data uploads (Fig. 3B). Those in the highest tertile for data uploads had a significantly greater decline in A1C than those in the lowest tertile (-2.1 ± 1.1 vs. $-1.1 \pm 1.7\%$; $P < 0.05$). Persistent and intermittent users and those who had greater or fewer data uploads did not differ with regard to baseline demographic or biochemical parameters.

A similar number of participants in each group experienced severe hypoglycemia during the study, defined as an episode of hypoglycemia that required assistance from another person (web-based: 46 events in 13 participants [median: 3 per participant]; usual care: 33 events in 11 participants [median: 2 per participant]).

Changes in blood pressure

Treatment for hypertension was targeted by the web-based care management intervention. Hypertensive participants in the web-based group ($n = 37$) had a significantly greater decline in systolic blood pressure after 12 months when compared with the usual care group ($n = 35$) (-10 ± 17 vs. -7 ± 21 mmHg; $P < 0.01$). Diastolic blood pressure declined similarly in both groups (web-based group: -5 ± 13 mmHg [$P = 0.053$ vs. baseline]; usual care group: -6 ± 11 mmHg [$P = 0.058$ vs. baseline]). The frequency of website log-ins or data uploads was not a predictor for change in blood pressure over time. At the end of the trial, there were fewer hypertensive partici-

pants in the web-based group ($n = 28$) than in the usual care group ($n = 37$).

Changes in lipid profiles

LDL cholesterol was analyzed as a secondary end point and did not change in either group (web-based group: -6 ± 12 mg/dl; usual care group: -5 ± 11 mg/dl). However, web-based care management was associated with a significant increase in HDL cholesterol (3 ± 6 mg/dl; $P < 0.05$ vs. baseline) and a significant decrease in triglyceride levels (-38 ± 99 mg/dl; $P < 0.01$ vs. baseline); these values did not change in the usual care group (1 ± 6 mg/dl and -2 ± 60 mg/dl, respectively).

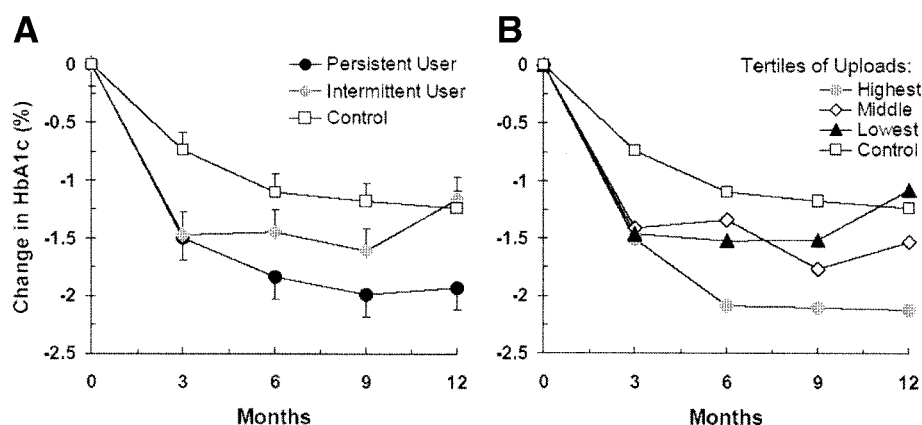


Figure 3—Effects of engagement with web-based care management and outcome. A: Changes in A1C in the web-based group who were persistent and intermittent users in comparison with the usual care group. Persistent users had a substantially greater fall in A1C compared with intermittent users and a significantly greater effect versus those receiving education and usual care. Data are means \pm SE. B: Changes in A1C in the web-based group by tertiles of website data uploads during the study. (Median number of uploads for each tertile: lowest = 1 upload; middle = 18 uploads; highest = 31 uploads.) A larger number of data uploads was associated with a larger decline in A1C.

CONCLUSIONS—More than most chronic diseases, diabetes often requires behavioral and medication changes supported by frequent feedback and support from care providers. We and others have previously shown that self-management education alone can result in significant improvement in A1C in patients with poorly controlled diabetes (19–21). In this study, we used broad eligibility criteria to produce potentially generalizable findings. Most of our study participants had no prior computer experience and/or Internet access. For the subjects who had elevated A1C, self-management education coupled with Internet access, technology training, and web-based care management resulted in significant improvements in A1C over 12 months when compared with education and usual care. Individuals who persisted with website usage and regular data uploads were more likely to achieve and maintain reductions in A1C. Additional improvements were seen in lipid profiles and systolic blood pressure in hypertensive participants. These findings support a role for web-based care management in patients with elevated A1C as a tool for improving diabetes care.

Several factors should be considered in interpreting the results of this feasibility study. Not every clinical practice setting has access to a care manager with similar training and experience as was available in this study, although such allied health professionals are likely to be-

come increasingly prevalent. We were able to provide Internet access and computer training to study participants, which may not be available to some patients. There was a low prevalence of women recruited into this study, reflecting the relatively smaller number of women cared for in the VA healthcare system. Previous studies (7,8) with a more balanced enrollment of men and women receiving care management have shown similar outcomes between men and women. The study question necessitated an open-label design that may have been subject to the Hawthorne effect and confounding factors. The observation that the degree of improvement in A1C correlated with level of interactivity with the website could reflect an underlying change in motivation of the participants rather than use of the care program per se. Consequently, although the evidence linking website use and outcome is noteworthy, the mechanism through which the care management program achieved its success remains speculative.

There was significant improvement in A1C among those randomized to education and usual care. The VA healthcare system has progressively improved its diabetes care program through a series of successful initiatives (22,23). In addition, the laboratory results obtained for this study were available on the VA electronic medical record database and could have resulted in targeted care that might not have been offered in its absence.

Care management has been embraced for patients with high-risk and/or high-cost medical conditions such as diabetes, with claims of significant cost savings (2,3). However, the cost-effectiveness of care management in diabetes is still a matter of debate. Indeed, a recent analysis of potential interventions in diabetic patients concluded that care management has an unclear economic impact (24). Nevertheless, care management has been recommended by the Task Force on Community Preventive Services of the Centers for Disease Control and Prevention (25). Although a detailed economic analysis is clearly warranted, our study results show the effectiveness of such an approach, particularly among individuals interested in engaging with the technology.

The Internet has clearly become the gateway to limitless health information (11–14). However, few studies have evaluated the clinical benefit of using web-

based education and/or healthcare provider feedback. Access to an interactive asthma education website resulted in a significant increase in asthma knowledge and reduced numbers of symptom-days, emergency room visits, and inhaled corticosteroid doses (26). In a trial linking web-based education with health care provider feedback, overweight and obese adults randomized to web-based behavioral counseling or basic Internet access achieved significantly greater weight loss when receiving web-based provider feedback intervention (15).

The major advantages of a web-based care management program are the ability to post professionally vetted material on secure websites, 24 h accessibility, and availability to individuals in their home without regard to the distance from their site of healthcare. Our results support the development and greater study of this increasingly ubiquitous portal in the management of patients. Patients with poorly controlled diabetes who adopt such a system and regularly exchange information with their healthcare providers are likely to derive important clinical benefits.

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Human Factors Analysis: Joslin Vision Network Comprehensive Diabetes Management Program

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INTRODUCTION

Since 2001, the Joslin Diabetes Center, the Department of Defense, the VA Boston, the Indian Health Service, and Estenda Solutions have been collaborating to develop an Internet-based informatics tool called the Comprehensive Diabetes Management Program (CDMP). The CDMP has many functions:

- Generates "alerts" when a patient has experienced a particular health event or when the results from a patient's laboratory test fall outside a pre-determined clinical range
- Incorporates a patient monitoring system allowing patients to upload self-monitoring data for analysis, as well as providing prompt feedback through reports and messages to realize personalized care and best-practice decision support
- Provides an overall clinical risk stratification of each patient. The stratification indicates whether and how the patient is above or below established goals in certain areas, such as glycemic control, blood pressure, and lipids
- Contains a Behavioral Assessment questionnaire intended to augment the clinical data in the CDMP and help care managers and patients identify possible barriers to care
- Contains a number of features intended to assist the care manager in the organization of his or her caseload, such as daily reminders, snapshots of the patients' conditions, and care plans
- Provides reports on almost any diabetes related performance metric at the provider, group, or implementation level

Given the breadth of the CDMP and its potential role in the care of people with diabetes, it is important to determine whether the CDMP is "user-friendly" and compatible with diabetes care providers' normal workflow and to modify it if it is not. Is the interface of the human and the machine/information system fully optimized to make the system easy to use, efficient, easy to learn, and easy to remember? Indeed, these types of questions about usability are pertinent for any new device or application and can enable correction of problem areas before the new device or application has widespread use. This poster describes the methodology and some of the results to date of a human factors study intended to address some of these usability questions. The human factors study followed an Expert Review that had already been conducted on the application. The purpose of the usability study is to target areas for improvement.

OBJECTIVES



Figure 1. Usability testing taking place



Figure 2. CDMP Patient Status, Clinical, and Behavioral Overview (i.e., Patient Snapshot)

The objectives of the human factors analysis/usability study (see Figure 1 for an example) were to discover how users interpreted the CDMP (see Figure 2 for a sample page of the CDMP application) and to enable us to identify ways to enhance the CDMP's functionality. Specifically, our goals were to identify ways to:

- Enhance how accurately users interpret the CDMP system to bring users' expectations in line with the system's actual functionality (Conceptual model)
- Enhance the performance of the CDMP to minimize user frustration and maximize user efficiency (Navigation and information architecture)
- Reduce user confusion and maximize user comprehension of the CDMP content (Content and terminology)

The findings will be used to make enhancements to the CDMP prior to a second round of usability testing.

METHODOLOGY & COMPONENTS OF USABILITY TESTING

Overview

- We conducted a usability test with diabetes care providers under controlled laboratory conditions (Figures 1 and 3).
- We recruited 6 subjects (Table 1) for this study and will recruit 4 more to test any resulting modifications. Usability tests typically rely on small samples of approximately 8 subjects. This is typically sufficient for determining the major usability issues.
- During the testing sessions, each study participant worked with a prototype version of the CDMP in a single session lasting approximately two hours.
- The prototype was populated with "real" diabetes patients (anonymized) to simulate what diabetes providers are likely to encounter day-to-day.
- We asked participants to perform information retrieval and interpretation tasks.
- We then observed how participants approached these tasks and documented their comments and subjective ratings about completing the tasks.
- Additionally, we administered a questionnaire to each participant. The questionnaire has 25, Likert-scale questions covering appeal, content, ease of use, performance, and support.
- Modification of the application and follow-up usability testing are ongoing.

Profession	Employment Setting	Percent of Patients with Diabetes
RN	Home health care nurse	10%
RN	Urban hospital	40%
RN, Diabetes Educator	Urban hospital	100%
MD	Urban hospital	90%
RN, Diabetes Educator	Urban outpatient clinic	100%
NP, Diabetes Educator	Urban Hospital	100%

Table 1. Main characteristics of study participants



Figure 3. Example of a tester learning the "think aloud" procedure

Testing Environment

- Testing was performed in a one-on-one interview setting.
- Each lab session tracked the testers' mouse movements and keyboard strikes.
- We also recorded testers' verbal comments with audio recording equipment.
- The testing lab is adjacent to a control / observation room, separated from the lab by a one-way mirror, so observers watched each session unobtrusively.

Usability Testing and the "Think-Aloud" Procedure

- Usability testing enabled us to observe users performing a set of standardized, common tasks in a controlled setting.
- We trained each user to use the "think-aloud" procedure so that we could follow their thought processes as they navigated CDMP.
- Users thought aloud as they performed a series of tasks. Sample tasks included:
 - Please locate a summary of David Barmhall's medical history. Barmhall is our fictitious patient for the study.
 - Locate a summary of David's history of medications.
 - View David's lab data. Graph a lab test (LDL). Print the results of David's labs.
 - Please create a Care Plan for David based on the information you have.
 - Add the following action items to the Care Plan: Order an A1c test, refer David to a podiatrist, and create a reminder to yourself to provide a referral to a health literacy counselor.

RESULTS & CONCLUSIONS

Results

Positive Findings

- Testers were enthusiastic about the layout of the application, the types of data available on the application's clinical pages, and the application's ability to share patient data among team members.
- Testers were able to successfully complete tasks that required them to locate existing clinical data for a specific patient.
- Testers found it easy to read and understand the patient-specific clinical pages.
- Testers wanted and expected the ability to customize the CDMP for their own use. This is a positive finding as the application was designed for such customization. It will be customized at each site that uses it at the time of implementation.
- Testers did not quickly grasp all concepts (i.e., the Care Plan, Alerts, Reminders and some CDMP-specific rating scales). Given testers received only a brief training, it remains to be determined whether full training in the application would increase speed of understanding.

Findings Suggesting Areas for Improvement

- Testers' presuppositions about what the application could do were not always congruent with the application's functionality. This suggested concrete ways that we might refine the application and/or develop training materials.
- Testers thought certain lists (such as "Action Items" for patients and care managers) were not as intuitive or clear.
- Testers thought that drop-down menus were not an appropriate tool for items where they wanted to make more than one choice.
- Testers thought error messages should be easier to read.
- Testers thought that items unique to the CDMP (e.g., ratings scales) should be explained clearly so that even long-time users of the application may interpret the information correctly.

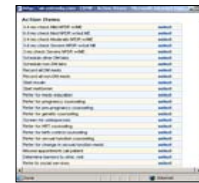


Figure 4. Example of page generating summary finding #7.



Figure 5. Example of page generating summary finding #10.

Conclusions

This study examined testers' perspectives on the CDMP's conceptual model, information architecture, navigation and content. The findings are being used to enhance the CDMP prior to further testing and rolling the application out to a large user population. Thus, it is likely that this study will result in significant cost savings because problems were identified before large-scale implementation took place.

To our knowledge, there has been no other research effort comparable to this one. There have been a large number of studies related to user interface design of other systems and considerable effort has been expended in developing applications to suit a variety of medical purposes; however, we are not aware of any comprehensive studies on the overall human factors consideration for a system with the purpose and functionality, and intended mode of application and operation as the CDMP, and certainly none directly examining the CDMP. We believe this study can provide a model for others who are developing large-scale applications for disease management.